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University  
of Glasgow

**Living with a severe mental illness and heart failure: An  
Interpretative Phenomenological Analysis.**

**&  
Clinical Research Portfolio**

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*Submitted in partial fulfilment of the requirements for the degree of  
Doctorate in Clinical Psychology*

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# **CHAPTER ONE**

## **SYSTEMATIC REVIEW**

**Characteristics and effectiveness of interventions aimed at improving self-care behaviours in patients with heart failure: A systematic review of randomised controlled trials.**

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Written according to guidelines for submission to the European Journal of Heart Failure. (See Appendix 1 for a summary of author instructions).

## Abstract

**Background:** There are approximately 900,000 people in the United Kingdom living with heart failure (HF). Adhering to the treatment regime for HF can be challenging. Non-adherence is common in relation to taking medication, following a suggested diet plan, and a failure to seek medical care when symptoms begin to escalate. These are all aspects related to self-care. Engaging in self-care behaviours may improve quality of life, medication adherence, reduce hospital admissions and reduce mortality.

**Aim:** The current review attempted to identify and synthesise randomised controlled trials (RCTs) investigating interventions designed to try to improve self-care behaviours in people with HF.

**Methods:** Nine computerised databases (Cochrane Library, OVID Medline, OVID Embase, EBSCO CINAHL, EBSCO Psycinfo, EBSCO Psycarticles, EBSCO Psychology and Behavioral Sciences Collection, Web of Science and Google Scholar) were searched from the start date of the respective database to 4<sup>th</sup> January 2018.

**Results:** Thirteen RCTs met inclusion criteria and were assessed to determine their risk of bias. Eleven of these studies involved an education and skills building programme, led by nursing staff either via telemonitoring, outpatient visits, home visits, and/or telephone calls. Two studies involved developing participant specific goal-based outcomes, and supporting participants to achieve goals. The results suggest that people are more likely to engage in self-care behaviours when they get extra support and education from nursing staff than when they simply attend routine outpatient appointments. However, risk of bias was identified in all but one study, with 10 of the 13 studies being assessed as 'High' risk of bias.

**Application:** Further research should aim to quantify the optimum length of input that people should receive following diagnosis of HF and discharge from hospital. Also, to determine the optimum number of home visits or telephone visits that people should receive. This area of research would also benefit from improvements in designing and reporting bias-reducing methods.

**Key words:** Heart failure, self-care, randomised controlled trial

## **Introduction**

Heart failure (HF) occurs when the heart fails to pump blood around the body as effectively as it used to (The British Heart Foundation; BHF). According to the British Society for Heart Failure, there are approximately 900,000 people in the United Kingdom living with HF. It causes or complicates about 5% of all emergency admissions and it consumes approximately 2% of the total NHS expenditure (British Society for Heart Failure; 2013/2014 NHS standard contract). Most of the care required for people with HF is related to hospital readmissions as a result of exacerbations in HF symptoms. The main factors contributing to this are non-adherence to a broad range of health behaviours including medication use and dietary control, and a failure to seek medical care when symptoms begin to escalate (Moser, Dickson, Jaarsma, Lee et al., 2012). These factors have been identified as components contributing to self-care (Harkness, Spaling, Currie, Strachan & Clark, 2015; Moser et al., 2012; Riegel, Moser, Anker et al., 2009).

Self-care can be defined as a 'rational process, involving purposeful choices and behaviours, reflecting knowledge and thought' (Riegel & Dickson, 2008). It is a proactive process, involving compliance with professional advice, paying close attention to one's body, and responding to symptoms appropriately. Self-care is considered essential in the management of chronic illness. Riegel and Dickson (2008) noted that for people with HF, repeated hospitalisations was attributed to poor self-care. They developed a 'Situation-Specific' model of HF, which identifies three separate, but related processes that people must engage with for effective self-care management. The first process involves engaging in self-care maintenance behaviours, such as, medication management, following suggested diet and fluid restrictions, engaging in daily exercise and monitoring symptoms daily (Buck, Harkness, Wion, Carroll et al., 2015). The second process involves successfully detecting physical symptoms and interpreting what they mean. Finally, responding to the symptoms appropriately is the process of self-care management (Riegel et al., 2016).

Riegel and Dickson (2008) highlighted that engaging in these processes effectively is influenced by factors related to the person, the problem and the environment. For example, factors such as peoples' experience or knowledge of the illness, the level of

social support they have, their attitudes, confidence, self-efficacy, the presence and severity of depression and anxiety and their physical functioning all influence the decisions people make regarding HF self-care (Harkness et al., 2015; Kessing, Denollet, Widdershoven & Kupper, 2016; Riegel, Lee & Dickson, 2011; Riegel et al., 2016). Therefore the decision-making process of self-care management is dynamic and influenced by many factors, and may explain why people find mastering self-care to be challenging.

The importance of supporting people to engage in these self-care behaviours is well recognised (Harkness et al., 2015; Riegel et al., 2016) and has been highlighted in guidelines across America and Europe in relation to treatment and management (Lindenfeld, Albert, Boehmer, et al., 2010; McKelvie, Moe, Ezekowitz, et al., 2012; McMurray, Adamopoulos, Anker, et al., 2012). Engaging in self-care behaviours has been shown to improve quality of life (QoL), improve medication adherence, reduce hospital visits and admissions and reduce mortality (Buck, Lee, Moser, Albert et al., 2012; Jovicic, Holroyd-Leduc & Straus, 2006; Lee, Carlson, & Riegel, 2007; Wang, Lin, Lee & Wu, 2011; Zambroski, 2008).

As mentioned, engaging in self-care behaviours can be challenging due to the personal, psychosocial and contextual factors that influence self-care (Riegel et al., 2009; Harkness et al., 2015). Qualitative research has attempted to better understand self-care behaviours in people with HF. For example, qualitative studies have attempted to explore self-care needs, and the strategies that people use to accommodate self-care recommendations into their daily lives. A meta-synthesis of qualitative research literature conducted by Harkness et al., (2015) recommended that healthcare providers should aim to provide a person-centred and individualised approach, to help support and encourage self-care strategies and behaviours. It also highlighted the value of caregivers for providing support to people with HF and encourages health systems to include caregivers, wherever possible, when trying to implement strategies and education around self-care (Harkness et al., 2015).

Quantitative studies have attempted to design interventions aimed at targeting key self-care behaviours. These studies have attempted to improve aspects of self-care behaviours known to be important for successful HF management. These studies are usually nurse-led interventions that involve educating people about their illness, and



providing guidance and advice to manage their treatment, and to monitor their symptoms. People are then monitored via home visits (HV), structured telephone support or telemonitoring (Buck et al., 2012; Clark, McDougall, Riegel, Joiner-Rogers et al., 2015). For example, a systematic review and meta-analysis by Clark, Inglis, McAlister, Cleland et al. (2007) concluded that introducing a telemonitor into patients' homes, to support them to monitor their symptoms, had a positive effect on clinical outcomes for people with chronic HF.

Objectively measuring self-care can be challenging. Self-care outcome measures attempt to measure change, or improvements in self-care behaviours, before and after an intervention. Two of the most common self-care outcome measures are the European Heart Failure Self-Care Behaviour Scale (EHFScB Scale) or the Self-Care of Heart Failure Index (SCHFI) (Buck et al., 2012; Riegel et al., 2009; Riegel et al., 2011). Such measures are useful in determining the effectiveness of interventions. However, the author is unaware of any quantitative review that synthesises interventions aimed at improving self-care behaviours for people with HF and which monitor and measure self-care outcomes using validated self-care outcome measures. Therefore, the current review attempted to identify and synthesise studies investigating interventions designed to try to improve self-care behaviours in people with HF. There is an increasing quantitative literature that aims to improve self-care outcomes in people with HF, therefore it was decided that, due to practical limitations, the review would focus on the most rigorous quantitative method, randomised controlled trials (RCTs).

### *Questions*

1. For people with a diagnosis of HF, what are the characteristics of interventions that have been designed to improve self-care outcomes?
2. What is the effectiveness of these interventions at improving self-care outcomes?
3. Do these interventions improve other aspects for people with HF, such as, quality of life, number of hospitalisations?

### **Method**

### *Search Strategy*

The following online databases were systematically searched for relevant articles: OVID Medline, OVID Embase, EBSCO CINAHL, EBSCO Psychinfo, EBSCO Psycharticles, EBSCO Psychology and Behavioral Sciences Collection, Web of Science and Google Scholar. The search was limited to randomised controlled trials (see Appendix 2 for search strategy to limit search to RCTs). The following search terms were used: “heart failure” OR “cardio-renal syndrome” OR “dyspnea, paroxysmal” OR “oedema, cardiac” OR “edema, cardiac” OR “heart failure, diastolic” OR “heart failure, systolic” AND “self-care” OR “self care” OR “self-manag\*” OR “self manag\*”. Online titles and abstracts were reviewed and duplicates removed. Articles were then examined to determine if they met eligibility criteria. The full text of potentially eligible papers were obtained. Hand searches of review papers were also conducted to identify any eligible studies. The reference section of papers that were identified by the electronic database searches were inspected to identify additional studies to be included in the review.

### *Inclusion and Exclusion Criteria*

Articles identified by the search strategy were screened using the following criteria:

#### Inclusion criteria:

- Journal article published in a peer reviewed journal
- Written in English
- Adults (aged 18 and above)
- Diagnosis of heart failure
- Methodology – RCTs only
- Self-care measured by previously validated instruments

#### Exclusion criteria:

- Review articles, books, book chapters and conference papers.
- Commentaries/descriptions, case studies/reports/unpublished theses/policy documents.
- No data, preliminary data, or qualitative data.
- Studies including family members/caregivers

### *Quality appraisal*

The Cochrane Risk of Bias Tool (Higgins Altman, Gotzsche & Juni, 2011; Lundh & Gøtzsche, 2008) was used to assess all eligible articles. Two assessors evaluated each article, assigning 'low', 'high' or 'unclear' risk of bias across all seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Evidence of each was recorded and where disagreement occurred consensus was reached via discussion. Where a decision could not be reached a third person (research advisor) provided a final opinion. Based on Higgins et al. (2011), an overall risk of bias was determined for each study. If a study was rated as 'High' risk of bias in one of the seven domains, it was judged to be overall 'High' risk of bias.

### *Effect sizes*

Effect sizes were calculated to determine differences in self-care scores between the intervention and control groups at final data collection point. Differences in scores were calculated using 'Cohen's d' equation (differences in means divided by pooled SD). Two studies (Clark et al., 2015; Shively et al., 2013) reported differences over time, however only Clark et al., 2015, included statistics. For this study, the effect size was calculated using the following equation:

$$Fdf_n > 1 \quad 2\sqrt{\frac{df_n F}{df_d}}$$

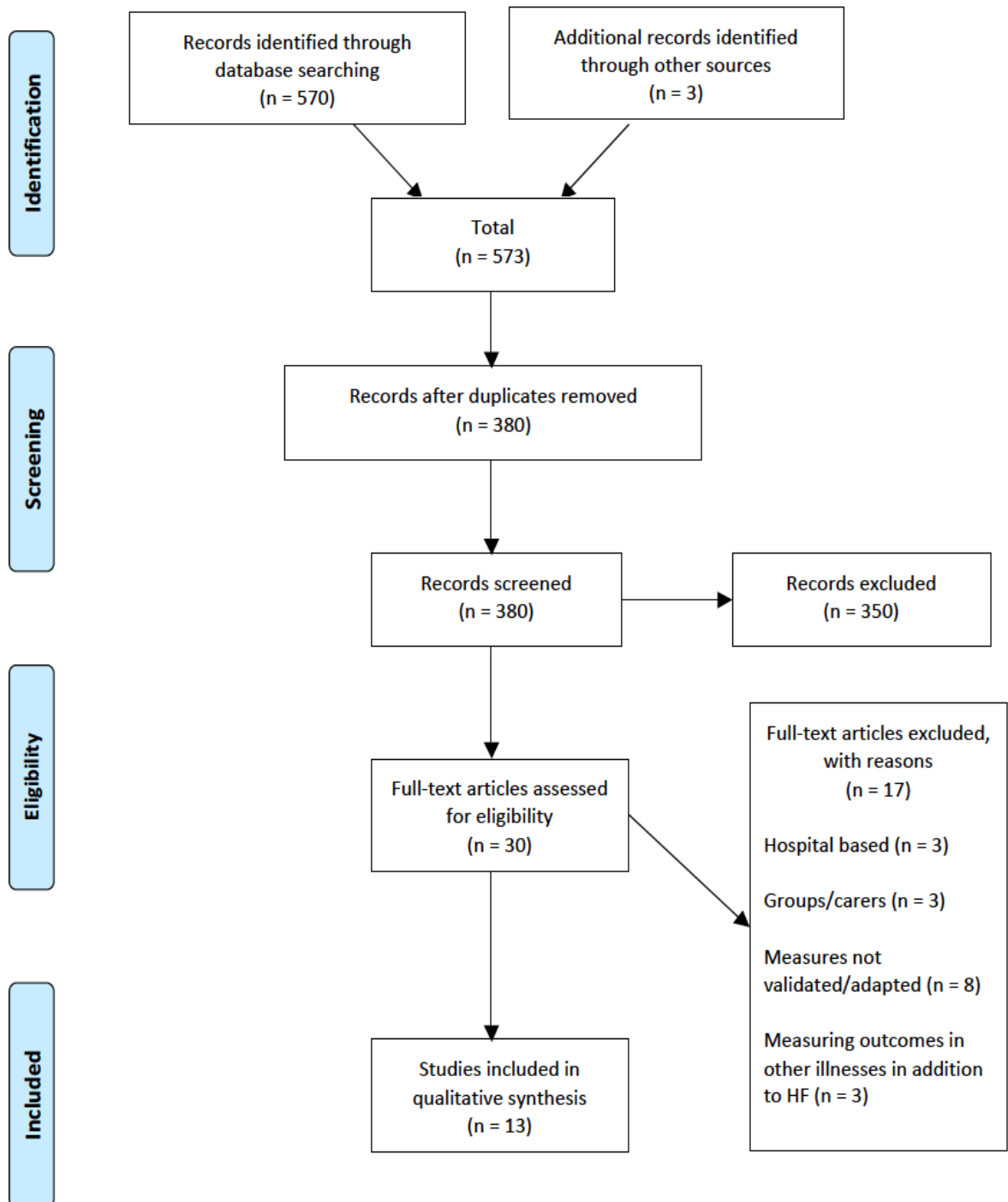
One study reported an effect size calculation (Creber et al., 2016). For some studies (Hoban et al., 2013, Clark et al., 2015, Creber et al., 2016; Shively et al., 2013) effect sizes could not be calculated due to a lack of data, or incomplete data. As a result, a meta-analysis could not be conducted. Authors were contacted via email to request additional data to enable effect sizes to be calculated.

## **Results**

Figure 1 provides an overview of the search, screen and eligibility assessment process followed within this review. A total of 570 studies were identified from database searches excluding duplicates, a further 3 studies were identified via hand searches of the reference lists of key articles, giving a total of 573 studies. Of these, 193 duplicates were extracted using a manual hand search. A further 350 were excluded

following a review of the article abstracts. Thirty full articles were subsequently assessed for eligibility and 17 further studies were excluded. A final total of 13 articles were included for data extraction and evaluation. A hand search of the reference list of the 13 identified studies found no additional papers. Table 1 provides relevant details of study design and findings. The selection included international research from seven countries across four continents: Europe (2), North America (5), Asia (3), and South America (3).

**Figure 1.** PRISMA (2009) Flowchart of the article selection process



### *Participant characteristics*

A total of 2160 participants were included in the 13 studies. Of these, 844 (39%) were female and 1316 (61%) were male. The smallest sample size was 33 (Oliveria, Cordeiro, Rocha, Guimaraes et al., 2017) and largest sample size was 602 (Dracup, Moser, Pelter, Nesbitt et al., 2014). The mean age of participants was 61.3 years (60.0 – 80.6). Seven studies recruited patients from hospital following HF-related hospitalisation (Creber, Patey, Lee, Kuan et al., 2016; Hagglund, Lynga, Frie, Ullman et al., 2015; Mussi, Ruschel, Souza, Lopes et al., 2013; Oliveria et al., 2017; Rahmani, Moradi, Aghakarimi & Hossain-Gholipour, 2017; Souza, Rohde, Ruschel, Mussi et al., 2014; Yu, Lee, Stewart, Thompson et al., 2015). Three studies recruited from outpatient units (Boyne, Vrijhoef, Spreeuwenberg, De Weerd et al., 2014; Sezgin, Mert, Ozpelit & Akdeniz, 2017; Shively, Gardetto, Kodiath, Kelly et al., 2013). Finally, three studies recruited from a mixture of outpatient clinics, hospitals, media, senior centres and assisted living facilities (Clark, McDougall, Riegel, Joiner-Rogers et al., 2015; Dracup et al., 2014; Hoban, Fedor, Reeder & Chernick, 2013).

The primary diagnosis for inclusion in the studies was HF, clarified by the studies as a formal clinical diagnosis of HF such as Acute Decompensated HF (ADHF), HF stage-C, Heart Failure reduced Ejection Fraction (HFrEF) or Heart Failure with preserved Ejection Fraction (HFpEF). Seven studies used the New York Heart Association (NYHA) functional classification system to identify the diagnosis. Comorbidities were reported by six studies. The most common comorbidities were: hypertension, diabetes, Chronic Obstructive Pulmonary Disease (COPD), renal disease, depression and chronic pain (Creber et al., 2016; Dracup et al., 2014; Hagglund et al., 2015; Mussi et al., 2013; Oliveria et al., 2017; Yu et al., 2015). Seven of the studies did not report whether the participants had any comorbidities (Boyne et al., 2014; Clark et al., 2015; Hoban et al., 2013; Rahmani et al., 2017; Sezgin et al., 2017; Shively et al., 2013; Souza et al., 2014).

**Table 1: Characteristics and findings of studies**

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
Boyne et al., 2014 (The Netherlands)	382 randomised (156 females 226 males)  Intervention n =197 (mean age = 71.0)  Control = 185 (mean age = 71.9)	Usual medical care	Telemonitoring device – pre-set dialogues and questions about symptoms, knowledge, behaviour. Educational/intensive symptom monitoring programme followed.	12-item EHFSB scale  Data collected: Baseline, 3m, 6m, 12m	Dutch HF knowledge Scale  Barnason Efficacy Expectation Scale  HF Compliance scale	Significant difference at 12m:  Intervention: M=17.4 (SD=4.5)  Control: M=20.8 (SD=5.8)  <u>Cohen's d = 0.66</u> (Effect size calculated)
Clark et al., 2015 (USA)	50 randomised (26 female 24 male)  Intervention: n = 25 (mean age = 61.7)  Control: n = 25 (mean age = 63.0)	Usual medical care	9-month intervention. 1 <sup>st</sup> phase (3 months): educational and skill building programme. 2 <sup>nd</sup> phase (3 months): telephone contact, no home visits. 3 <sup>rd</sup> phase (3 months) no home visits or telephone	15-item SCHFI  Baseline, 3m, 6m and 9m	KCCQ  GDS  Metamemory in Adulthood Questionnaire  HFKT	Self-care maintenance: difference non-significant  <u>Effect size d=0.40</u> (Effect size calculated)  Self-care confidence: Improvement significantly greater in intervention than control (F = 6.70, df = 3, 43, p = .001)  <u>Effect size d=0.68.</u> (Effect size calculated)

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
			contact, patient required to communicate with physician if questions arose.			Self-care management: scores over time not reported: time 3 only, mean rank reported (intervention=12.22, Control=6.78) <u>Mann Whitney U = 16.00, df = 1, p = .03.</u>
Creber et al., 2016 (USA)	100 randomised (20 females 47 males)  Intervention n = 41 (mean age = 60)  Control n = 26 (mean age = 63)	Usual medical care.	Motivational Interviewing programme: Identify at least 2 specific goals, plan for accomplishing goals set out and reinforced in the follow-up calls.	22-item SCHFI  Baseline, 90 days	HFSPS  KCCQ	Self-care maintenance: significant difference at end of intervention:  Intervention: M=19.7 (SD=16.0) Control: M=12.1(SD=18.3) <u>Cohen's d=0.44</u> (Reported in study)  Self-care confidence: difference non significant (data not reported)  Self-care management scores not reported
Dracup et al., 2014 (USA)	602 randomised (244 females 358 males)  Fluid watcher LITE: n =	Routine care. Given educational brochures, healthcare logbooks.	Fluid watchers LITE group – weight and HF symptoms diaries, educational session, medication, diet, self-monitoring, coaching. Two	9-item EHFSB scale  Baseline, 3m, 12m and 24m	Charlson Comorbidity Index  HF knowledge Scale  Short test of	At 24m no sig difference between control group and intervention groups:  Control group: M=23.15 (SE=0.54)  Fluid LITE group: M=21.92 (SE=0.56)



Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
	<p>200 (mean age = 65.9)</p> <p>Fluid watcher PLUS: n = 193 (mean age = 66.1)</p> <p>Control: n = 209 (mean age = 66.4)</p>		<p>phone calls at 2-week intervals.</p> <p>Fluid watcher PLUS group – as above plus audiotape of education session and bi weekly follow up phone calls.</p>		<p>Functional Health Literacy in Adults</p> <p>Hospitalisations</p>	<p><u>Cohen's d = 0.16</u> (Effect size calculated)</p> <p>Fluid LITE plus group: M=21.85 (SE=0.56)</p> <p><u>Cohen's d = 0.16</u> (Effect size calculated)</p>
Hagglund et al., 2015 (Sweden)	<p>82 randomised (26 female 56 male)</p> <p>Intervention n = 32 (mean age = 75.0)</p> <p>Control n = 40 (mean age = 76.0)</p>	Usual medical care.	Home Intervention System (HIS). Info on weight, drug dose, lifestyle advice, contact details for info and support, and tips on how to improve living with HF. Patient could evaluate their own perceived health.	<p>9-item EHFSB scale</p> <p>Baseline, 3m</p>	<p>HRQoL</p> <p>KCCQ</p> <p>SF-36</p> <p>Dutch HF Knowledge Scale</p>	<p>Significant improvement in intervention scores compared with control group</p> <p>Intervention: median=17(IQR: 13, 22) Control: median=21(IQR: 17, 25)</p> <p>Estimated means calculated on: <a href="http://vassarstats.net/median_range.html">http://vassarstats.net/median_range.html</a></p> <p>Estimated means: Intervention: M=17.25 (SD= 2.6) Control: M=21 (SD=2.45)</p>

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
						<u>Cohen's d = 1.53</u> (Effect size calculated)
Hoban et al., (2013)  (USA)	80 randomised (51 female 29 male)  Intervention n = 40 (mean age = 76.1)  Control n = 40 (mean age = 80.6)	Usual care – nursing visits 2/3 times per week.	Telemonitoring. Patients taught how to take BP and heart rate. Written educational booklet provided. Patients monitor daily or more frequently when needed.	22-item SCHFI  Baseline, 1m, 2m, 3m	MLHF	Report significant difference but statistics not reported.
Mussi et al., 2013  (Brazil)	200 randomised (74 females 126 males)  Intervention (n = 101 (mean age =62.49)  Control (n = 99, mean age = 63.37)	Routine follow-up.	Systematic follow- up by nurses specialised in HF patient care through home visits on the 10 <sup>th</sup> , 30 <sup>th</sup> , 60 <sup>th</sup> and 120 <sup>th</sup> day after discharge, 4 HV's and 4 telephone calls	12-item EHFScB scale  Baseline, 1m, 2m, 4m	Clinical congestion score  HF knowledge questionnaire	Significant improvement for both groups and at 4m – scores sig. better in intervention compared with control group:  Intervention: M=22.36 (SD=6.46) Control: M=30.91 (SD=7.30)  <u>Cohen's d – 1.24</u> (Effect size calculated)

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
Oliveria et al., 2017 Brazil	44 randomised (30 males, 14 females)  Intervention n = 19 (mean age = 60.5)  Control n = 17 (mean age = 60.0)	Standard outpatient monitoring at HF clinic	12 telephone calls, weekly, then bi weekly for the following 2 months. Pharmacological and non-pharmacological adherence was discussed and info about the disease and self-care were provided.	12-item EHFSB  Baseline, 2m, 4m	HF knowledge questionnaire	At 4m: sig difference in intervention compared to control group  Intervention: M=25.4 (SD=6.6) Control: M=29.5 (SD=4.8)  <u>Cohen's d = 0.71.</u> (Effect size calculated)
Rahmani et al., 2017 (Iran)	80 randomised (46 female 34 male)  Intervention n = 40 (mean age = 67.5)  Control n = 40 (mean age = 69.47)	Routine care	Continuous care model Four phases:  1). Orientation-understanding of the problem, motivating and discussion of follow-up process. 2). Educational content via telephone, lectures, booklets, training package, CD's. 3). Follow up via telephone every	22-item SCHFI  Baseline, 1m, 3m.	None	At 3m: Sig. improvement in scores for intervention group but not control group.  <u>Maintenance:</u> Scores sig. better in intervention group compared with control group:  Intervention: M=49.86 (SD= 12.58) Control: M=23.39 (SD=10.83)  <u>Cohen's d=2.26</u> (Effect size calculated)  <u>Management:</u> Scores sig. better in intervention group than control

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
			week for three months. 4). Evaluation phase – month after intervention.			group:  Intervention: M=55.38(SD=15.06) Control: M=34.50(SD= 10.24)  <u>Cohen's d =1.65</u> (Effect size calculated)  <u>Confidence:</u> Scores sig. better in intervention group compared with control group:  Intervention: M=45.82 (SD=16.27) Control: M=29.51 (SD=21.98)  <u>Cohen's d=0.8</u> (Effect size calculated)
Sezgin et al., 2017  (Turkey)	90 randomised (21 females, 69 males)  Intervention n = 42 (mean age = 60.75)  Control n = 44 (mean age = 65.86)	Standard care	Educational booklet, daily follow-up chart to record weight, edema status, BP, pulse, medication. Magnet-held set provided to record factors/situations that may require visit to clinic/emergency	22-item SCHFI  Baseline, 3m, 6m	LVDS  Rehospitalisation	At 6m, sig difference in scores between intervention group compared with control group:  <u>Maintenance:</u> Intervention: M=71.54 (SD= 19.50) Control: M=40.21(SD=14.43)  <u>Cohen's d=1.8</u> (Effect size calculated)  <u>Management:</u> Intervention:

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
			room. Phone calls every 2 weeks for 6 months.			<p>M=63.33(SD= 21.37) Control M=29.00(SD= 17.98)</p> <p><u>Cohen's d = 1.74</u> (Effect size calculated)</p> <p><u>Confidence:</u> Intervention: M=69.68(SD=22.54) Control: M= 42.99(SD=16.90)</p> <p><u>Cohen's d=1.35</u> (Effect size calculated)</p>
Shively et al., 2013 (USA)	<p>84 randomised (1 female 83 males)</p> <p>Intervention n = 43 (mean age = 63.4)</p> <p>Control n = 41 (mean age = 68.9)</p>	Routine medical care	Tailored programme of individualised self-selected goals and moving the patient to a higher level of activation. Health behaviour goals determined, progress towards goals was reinforced. Self-management tool kit provided.	<p>15-item SCHFI</p> <p>Baseline, 3m, 6m</p>	<p>PAM</p> <p>MOS</p> <p>Specific Adherence Scale</p> <p>Hospitalisations</p> <p>Emergency department visits.</p>	<p>No significant group by time interactions for self-care maintenance, management or confidence scales and no significant interaction effects for group by PAM level by time interaction for SCHFI scales.</p> <p>(Statistics not reported)</p>
Souza et al., 2014	252 randomised	Standard treatment	4 home visits and 4 telephone calls.	12-item EHFSB scale	HF knowledge questionnaire	Sig. better scores in Intervention than Control group at 6m:

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
(Brazil)	(94 females 158 males)  Intervention n = 123 (mean age = 62)  Control n = 129 (mean age = 63)	approach	Knowledge of disease, self-care behaviour adherence, weight control, hydro- saline restriction, physical and annual vaccination was the focus of HV's and telephone contact.	Baseline, 1m, 2m, 4m, 6m.		Intervention: M=22.7(SD=7.0) Control: M=30.2(SD=7.0)  <u>Cohen's d = 1.07</u> (Effect size calculated)
Yu et al., 2015  (China)	178 randomised (87 females 91 males)  Intervention group n = 90 (mean age = 78.6)  Control group n = 88 (mean age = 78.7)	Standard care	Pre-discharge visits, home visits, intensive telephone follow-up and telephone access to cardiac nurse. Educational and supportive interventions. Telephone call every 2 weeks for 3 months then every 2 months for 6 months.	18-item SCHFI  Baseline, 6 weeks, 3m, 9m.	Dutch HF knowledge scale  MLHFQ  EQ-5D	At 9m: Maintenance: Scores better in intervention than Control:  Intervention: M=53(SD=21.1) Control: M=40.1(SD=20.5) <u>Cohen's d = 0.62</u> (Effect size calculated)  Management: Scores better in intervention than control:  Intervention: M=80.0(SD=14.1) control: M=74.0(SD=16.6)  <u>Cohen's d = 0.39</u> (Effect size calculated)

Author (country)	Sample	Control group	Intervention Group	Self care measures and timeline	Other measures	Main Self-Care Finding and Cohen's d
						Confidence: Scores better in intervention than control:  Intervention: M=38.6(SD=20.6) Control: M=25.5(SD=15.1)  <u>Cohen's d = 0.73</u> <i>(Effect size calculated)</i>

*NB: Self Care outcome measure terms: European Heart Failure Self-Care Behaviour Scale (EHFScB scale) and Self-Care Heart Failure Index (SCHFI). Other outcome measure terms: Geriatric Depression Scale (GDS), EuroQol-5Dimensions (EQ-5D), Health Related Quality of Life (HRQoL), Heart Failure Knowledge Test (HFKT), Kansas City Cardiomyopathy Questionnaire (KCCQ), Left Ventricular Dysfunction Scale (LVDS), Left Ventricle Ejection Fraction measure (LVEF), Medical Outcomes Study (MOS), Minnesota Living with Heart Failure Questionnaire (MLHFQ), Patient Activation Measure (PAM), Short Form Health Survey 12 (SF-12), Swedish version of Health Survey (SF-36), Heart Failure Somatic Perception Scale (HFSPS).*

### *Characteristics of interventions*

All interventions were nurse-led and could be categorised as one of two broad forms. The first type of intervention involved education and skills building, with the aim of improving participants' HF knowledge, improving their ability to monitor their symptoms, for example, heart rate, blood pressure, weight, and finally, improving their self-care behaviours, such as adherence to medication, weight and dietary control, fluid control and levels of exercise. The method of delivery varied between studies. Three studies (Boyne et al., 2014; Hagglund et al., 2015; Hoban et al., 2013) delivered the educational content via a telemonitoring device, which was installed into the participant's home. The device included stored information about HF, treatment advice, medication dosage, and guidance to monitor symptoms. Participants could use the device to record and evaluate their own perceived health and to report any symptoms that they were concerned about. This was monitored by nursing staff, and was followed up by telephone contact. Five of the studies involved delivering the educational content and skills building via a combination of home visits (HV) and telephone calls (Clark et al., 2015; Mussi et al., 2013; Rahmani et al., 2017; Souza et al., 2014; Yu et al., 2015). Two of the studies (Sezgin et al., 2017; Oliveria et al., 2017) delivered the educational content via outpatient appointments. Finally, one study (Dracup et al., 2014) included two intervention groups, as well as the control group. The aim of this study was to investigate the impact of two different intensity levels of HF education and self-care enhancement.

The second type of intervention involved a tailored intervention approach, which focused on increasing motivation and activation levels. One intervention was based on Activation theory (Shively et al., 2013) and aimed to increase participants' activation levels by determining self-selected goals and increasing levels of activation over a six-month period. Creber et al's, (2016) study involved a Motivational Interviewing tailored intervention. Participants identified specific client-centred goals related to HF self-care and establishing a client-directed plan, setting smaller daily goals in the context of aiming to achieve the overall self-defined goal. Participants were supported by nursing staff to achieve their HF self-care goals.

As mentioned, the delivery and follow-up of educational content and monitoring of participants was either via a telemonitoring device, attendance at outpatient



appointments, HV's, telephone contact, or a combination of all of these methods. The number of outpatient appointments, HV's and telephone calls varied between studies. It was difficult to determine the number of contacts within studies. Of the studies which reported the number of contacts, the range was between 2-12 HV's and 4-19 telephone calls. Some studies identified that the number of contacts depended on level of need of the participants, those who required more support received more contact from nurses. This undoubtedly impacts the standardisation of the intervention.

All studies had one control group, which was described as treatment as usual (TAU) or routine care. It was difficult to determine the length of the interventions, however, the overall range of data collection was between three and 24 months, with an average of three time points for data collection (range 2 – 5). Four studies collected data up to three months (Creber et al., 2016; Hagglund et al., 2015; Hoban et al., 2013; Rahmani et al., 2017), two studies collected data up to four months (Mussi et al., 2013; Oliveria et al., 2017), three studies collected data up to six months (Sezgin et al., 2017; Shively et al., 2013; Souza et al., 2014), two studies collected data up to nine months (Clark et al., 2015; Yu et al., 2015), one study collected data for 12 months (Boyne et al., 2014) and one study collected data for 24 months (Dracup et al., 2014).

#### *Self-care outcome measures*

All thirteen studies administered one of two valid and reliable self-care outcome measures: the Self-Care Heart Failure Index (SCHFI, v4 and v6.2) (Riegel, Carlson, Moser, Sebern et al., 2014) or the European Heart Failure Self-Care Behaviour Scale (EHFScB scale) (Jaarsma, Stromberg, Martensson, & Dracup, 2003). There were three versions of the SCHFI administered (15-, 18-, or 22-items). It is a self-report scale with items rated on a four-point scale and divided into three subscales measuring self-care maintenance, self-care management and self-care confidence (Vellone, Riegel, Cocchieri, Barbaranelli et al., 2013). The EHFScB scale is either a 9- or 12-item scale, items rated on a five-point scale, which measures changes in behaviours over time. The scale is available in over 14 languages (Jaarsma et al., 2003).

#### *Self-care outcome results*

The majority of the results reported are based on differences in scores between the intervention group and control group at final data collection point. For two studies

(Clark et al., 2015; Shively et al., 2013) the results are based on improvements over time. Results are reported according to intervention type and outcome measure used to measure self-care. Five studies, which provided an education, skills building and nursing follow-up intervention, measured self-care outcomes using the SCHFI (Clark et al., 2015; Hoban et al., 2013; Rahmani et al., 2017; Sezgin et al., 2017; Yu et al., 2015). Three of these studies (Rahmani et al., 2017; Sezgin et al., 2017; Yu et al., 2015) reported significantly better self-care outcome scores in the intervention group compared with the control group by end of follow-up. This result was found in all three domains of the SCHFI: self-care maintenance ( $d=2.26$ ;  $d=1.80$ ;  $d=0.62$ ), self-care management ( $d=1.65$ ;  $d=1.74$ ;  $d=0.39$ ) and self-care confidence ( $d=0.8$ ;  $d=1.35$ ;  $d=0.73$ ). Clark et al. (2015) reported significantly improved scores over time for the intervention group compared with control group for self-care maintenance ( $d=0.40$ ) and self-care confidence scores ( $d=0.68$ ). In terms of self-care management scores, they reported an improvement over time in self-care outcome scores in intervention group but not control group ( $U=16.00$ ,  $df=1$ ,  $p=0.03$ ). Effect sizes could not be calculated for this result. Hoban et al. (2013) reported that patients in the intervention group showed higher scores in questions related to physical activity and weighing themselves more frequently, compared with control group, but no statistics or data were available to support this finding.

Six studies (Boyne et al., 2014; Dracup et al., 2014; Hagglund et al., 2015; Mussi et al., 2013; Souza et al., 2014; Oliveria et al., 2017) also involved educating participant's on HF knowledge, symptoms and behaviours, however, they measured changes in self-care behaviours using the EHFS<sub>CB</sub> Scale. By end of follow-up, five studies reported significant differences in self-care scores in the intervention group compared with the control group (see Table 1 for respective effect sizes). However, Dracup et al. (2014) found no significant differences between the intervention and control group by 24 months.

In relation to applying a motivational interviewing approach and developing client-centred goals, Creber et al. (2016) found that after three months, scores in self-care maintenance were significantly better in the intervention group compared with control group ( $d=0.44$ ). There was a difference in self-care confidence scores but the effect was non-significant ( $d=0.26$ ). They did not report differences in self-care management. The authors explained that patients reported being asymptomatic

therefore self-care management scores could not be calculated. Finally, in relation to aiming to improve self-care behaviours by increasing activation levels, Shively et al. (2013) reported no improvements in self-care maintenance, confidence or management between their intervention and control groups. Effect sizes could not be calculated for each self-care domain of the SCHFI.

#### *Other outcomes of interest*

In addition to self-care, studies were interested in the impact of the interventions on other outcomes, such as, number of hospitalisations (Dracup et al., 2014; Hoban et al., 2013; Sezgin et al., 2017; Shively et al., 2013; Souza et al., 2014), adherence (Boyne et al., 2014; Hagglund et al., 2015; Mussi et al., 2013) HF knowledge (Boyne et al., 2014; Clark et al., 2015; Hagglund et al., 2015; Mussi et al., 2013; Oliveria et al., 2017; Yu et al., 2015) QoL (Clark et al., 2015; Hoban et al., 2013; Sezgin et al., 2017) and cardiac death (Dracup et al., 2014; Souza et al., 2014; Yu et al., 2015).

In relation to number of hospitalisations, four studies (Dracup et al., 2014; Hoban et al., 2013; Sezgin et al., 2017; Yu et al., 2015) found no differences between offering education and skills building, compared with TAU. Improving activation levels was reported to have lowered number of hospitalisations in intervention group compared with control group, by end of follow-up (Shively et al., 2013). Education on HF knowledge was found to improve participant's knowledge compared with TAU group for four studies (Clark et al., 2015; Mussi et al., 2013; Oliveria et al., 2017; Souza et al., 2014). However Boyne et al. (2014) did not find this at 12-month follow-up. In terms of adherence to treatment plan, education intervention studies found that by end of follow-up, there was a significant improvement in adherence scores for intervention group but not control group (Boyne et al., 2014; Mussi et al., 2013). Two studies found that education and skills building improved QoL, compared with TAU (Clark et al., 2015; Hoban et al., 2013). However, Sezgin et al. (2017) did not find this to be the case. Finally, in relation to cardiac death, two studies, which provided education and nursing follow-up, did not find any differences in number of cardiac deaths, compared with control group (Dracup et al., 2014; Sezgin et al., 2017).

#### *Risk of Bias*

As mentioned, two assessors evaluated each article, assigning ‘low’, ‘high’ or ‘unclear’ risk of bias across all seven domains. Inter-rater agreement was high for all papers (89%) and any disagreements were resolved by discussion. Based on Higgins et al. (2011), an overall risk of bias was determined for each study (see Figure 2). All but three studies (Boyne et al., 2014; Dracup et al., 2014; Mussi et al., 2013) were rated as overall ‘high’ risk of bias. Only one study Dracup et al. (2014) was rated as having an overall ‘low’ risk of bias. It is important that these are taken into account when considering the results of the studies and as such, findings must be interpreted with caution. A detailed breakdown of the risk of bias ratings can be found in Appendix 3.

The areas of the lowest bias across all studies was in the domain of randomisation (69.2%). Method of randomisation was reported in all but four studies (Clark et al., 2015; Creber et al., 2016; Hagglund et al., 2015; Rahmani et al., 2017). Three areas were difficult to assess, mostly because studies failed to provide details. These were in relation to allocation concealment, and details about blinding of participants, personnel and outcome assessment. This information was rarely reported, 64.1% of the data was assessed as ‘unclear’ risk of bias.

‘High’ risk of bias was reported in four domains. In relation to blinding of outcome assessment, two studies (Clark et al., 2015 and Sezgin et al., 2017) highlighted that nurses involved in interventions also collected outcome measure data from participants. Three studies were assessed as ‘high’ risk of bias in the incomplete outcome data domain (Creber et al., 2016; Hagglund et al., 2015; Shively et al., 2013). These were related to high dropout, participant numbers not balanced across groups and missing data. In relation to selective reporting, five studies (Clark et al., 2015; Creber et al., 2016; Hoban et al., 2013; Rahmani et al., 2017; Shively et al., 2013) were assessed as being ‘high’ risk of bias in this domain, related to outcome data not being reported as expected, or missing data. Finally, for the ‘Other’ domain, seven studies were assessed as ‘high’ risk of bias, due to small sample sizes, no power calculation, equipment malfunctions, and method of selection (Clark et al., 2015; Hoban et al., 2013; Oliveria et al., 2017; Rahmani et al., 2017; Shively et al., 2014; Souza et al., 2014; Yu et al., 2015).

**Figure 2. Risk of Bias Assessment**

	SELECTION BIAS	PERFORMANCE BIAS	DETECTION BIAS	ATTRITION BIAS	REPORTING BIAS	OTHER BIAS	
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other
							Overall Risk of bias
Low Risk							
Unclear Risk							
High Risk							
Boyne et al. (2014)							
Clark et al. (2015)							
Creber et al. (2016)							
Dracup et al. (2014)							
Hagglund et al. (2015)							
Hoban et al. (2013)							
Mussi et al. (2013)							
Oliveria et al. (2017)							
Rahmani et al. (2017)							
Sezgin et al. (2017)							
Shively et al. (2013)							
Souza et al. (2014)							
Yu et al (2015)							

## Discussion

Self-care has been shown to be an important component in successful HF management (Harkness et al., 2015). This review attempted to identify and review RCTs that aimed to improve self-care behaviours in people with HF. Thirteen studies were identified that assessed self-care behaviours using either one of two measures: the SCHFI and the EHFS<sub>CB</sub> scale.

Despite a review by Boyde, Turner, Thompson and Stewart, (2011) which found variable results associated with providing education interventions and HF-related outcomes, 11 of the 13 studies reviewed involved providing an intensive education and skills-building package. Of these 11 studies, 10 reported significant improvements in scores related to self-care that lasted until the end of the follow-up period. Only one study (Dracup et al., 2014) reported no differences in self-care scores by end of follow-up. Interestingly, this study had the lengthiest follow-up period, 24 months. By 24 months, there were no differences in scores related to self-care.

Two studies attempted to improve motivation and activation levels of patients by focusing on goal-directed outcomes. Shively et al. (2013) found no improvements in the groups, and Creber et al. (2016) only found scores in the self-care maintenance domain to be significantly better in the intervention group compared with the control group.

Interestingly, the three studies which introduced a telemonitoring device into patients' homes to support them to monitor their own symptoms, reported significantly better self-care scores for patients who had the telemonitor device, compared with patients in the 'treatment as usual' groups (Boyne et al., 2014; Hagglund et al., 2015; Hoban et al., 2013). This supports a review of telemonitor support for patients with HF (Clark, Inglis, McAlister, Cleland, Stewart, 2007).

Risk of bias were identified in all but one study (Dracup et al., 2014). This was mostly due to lack of reporting information regarding blinding and information on reporting outcome data, which, as a result, required risk of bias to be assessed as 'unclear'. Ten studies received at least one score of 'high' risk of bias. This was due to reporting of outcomes, missing data, small sample sizes, biases between the groups and not

conducting power calculations. Overall, 10 out of the 13 studies received an overall ‘high’ risk of bias score, and these limitations need to be taken into consideration when interpreting and generalizing these RCT results. It is important to note that every study which reported ‘large’ effect sizes were also rated to be overall ‘High’ risk of bias. A review by Wykes, Steel, Everitt and Warrier (2008) highlights that methodological attributes, such as masking participants to groups, may impact and inflate the treatment effects. As such, the results from these studies should be interpreted with caution.

#### *Limitations of current review*

Several limitations of this review should be considered when interpreting its findings. Despite that every attempt was made to produce an exhaustive account of all of the relevant research on the topic, there is a possibility that some studies may have been missed. Added to this, there was no measure of inter-rater reliability at the abstract screening stage. While beyond the scope of this project, normal practice would be that more than one person would review all of the titles and abstracts of search results. This improves reliability but also reduces the chance for human errors. Unpublished studies were excluded from the review and it is important to consider that this which will have introduced publication bias. The decision to limit search criteria solely to include RCT designed studies provided a focused assessment and enabled risk of bias evaluation; however, the breadth of developing evidence aimed at improving self-care behaviours is unlikely to be fully represented. Other limitations of this review are related to the features of the individual studies. Even though every study highlighted the time points for collecting outcome measures, it was difficult to determine the difference between intervention length and follow-up period. Also, some studies were clear about the number of HVs and telephone calls that were made to participants, but some studies didn’t specify the number of HVs and telephone calls. There was also variation within studies in relation to the number of HV’s and telephone calls that participants received. This makes it difficult to draw firm comparisons and conclusions about what is an effective timescale to offer HVs and telephone calls in order to try to improve self-care behaviours.

#### *Clinical implications and future research*

Generally the results suggest that patients show better outcomes when they are given extra support in addition to standard outpatient appointments. Research suggests that patients tend to avoid seeking medical care when symptoms begin to escalate (Moser, Dickson, Jaarsma, Lee, Stromberg et al., 2012). Therefore, added support and input from nursing staff can monitor patients and encourage them to manage their symptoms better. A review by McAlister, Stewart, Ferrura and McMurry (2004), concluded that follow-up input from the multi-disciplinary team reduced mortality and all-cause hospitalisations. It would be interesting to attempt to quantify the optimum length of input that patients should receive following diagnosis of HF and discharge from hospital. Also, to determine the optimum number of HVs or telephone visits that patients should receive. These aspects were difficult to determine from review of included studies.

### *Conclusions*

This was the first review to synthesize RCTs examining the impact of interventions on improving self-care behaviours, using reliable and valid outcome measures to assess self-care behaviours. The findings suggest that patients may be more likely to engage in self-care behaviours when they get extra support and education from nursing staff than when they simply attend routine outpatient appointments. It is important to note that risk of bias was identified in all but one study. As a result, it is not possible to determine the effectiveness of self-care interventions without methodologically robust research.



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**CHAPTER TWO**  
**MAJOR RESEARCH PROJECT**

**Living with a severe mental illness and heart failure: An  
Interpretative Phenomenological Analysis.**

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## Plain English Summary

**Background:** People who have a severe mental illness (SMI) are two to three times more likely to develop a heart problem, such as heart failure (HF). At present there is no qualitative research investigating peoples' experiences of living with a SMI and HF.

**Aims:** This study aimed to explore peoples' experience of living with both a SMI and HF. It aimed to understand individuals' understanding of their illnesses and the factors influencing how they manage the demands of these illnesses.

**Methods:** Three people with a diagnosis of an SMI and HF were interviewed. Semi-structured interviews were used, enabling the researcher to explore their experiences in greater depth. The interviews were recorded, transcribed and analysed using Interpretative Phenomenological Analysis, which emphasises the importance of individuals' experiences and how they makes sense of these experiences.

**Results:** Three main themes were identified from the participants' accounts. These themes were focused on the experience of being ill, changes and adjustments that were made as a result of being ill, and the role of others in helping to manage their illnesses.

**Applications:** Participants described a range of experiences and it is hoped that these findings can inform developments in relation to the care that individuals receive from healthcare professionals working in both mental and physical healthcare settings. This study has highlighted a need for greater integration between mental and physical health.

## Abstract

**Background:** People living with a severe mental illness (SMI) are at greater risk of developing heart failure (HF) than the general population. Reasons for this are complex however antipsychotic medication, poor diet, sedentary behaviour, smoking, use of alcohol contribute to increased risk. At present little is known about the experience of people living with both of these illnesses.

**Aims:** The aim of this study is to describe the experience of people with a SMI and HF. Specifically, to determine individuals' understanding of their illnesses and the factors influencing their ability to manage their illnesses.

**Methods:** The study was designed following the principles of Interpretative Phenomenological Analysis (IPA). Three participants provided their informed consent to participate in semi-structured interviews exploring their experiences of living with a SMI and HF. Interviews were transcribed and analysed in line with IPA methodology.

**Results:** Three main themes were identified from the participants' accounts. The first theme was focused on the experiences of becoming ill, trying to make sense of and coming to terms with their illnesses. The second theme was related to the changes and adjustments that were made as a result of being ill, such as lifestyle changes. The third theme identified the importance of others in supporting participants to manage their illnesses. The themes were inter-related by the emotions experienced by participants across all three themes.

**Applications:** Participants' accounts provided valuable insights into the complex nature of comorbidity, and highlighted implications for clinical practice, service provision and future research.



## **Introduction**

There is longstanding evidence to suggest that people living with a severe mental illness (SMI), such as schizophrenia or bipolar disorder, are less likely to have their physical health needs identified, or to receive appropriate treatment for these (The King's Fund; Mitchell & Lord, 2010; Smith, Langan, McLean, Guthrie & Mercer, 2013). Heart Failure (HF) is a cardiac condition that occurs when the heart fails to pump blood around the body as effectively as it used to (The British Heart Foundation; BHF). HF is one of the predominant causes of the 10- to 20- year reduction in life expectancy for people with a SMI (Crump, Winkleby, Sundquist & Sundquist et al., 2013; Laursen, 2011; Lawrence, Hancock & Kisely, 2013). Risk factors associated with prescribed antipsychotic medication and also behavioural health risks such as poor dietary habits, smoking, use of alcohol, obesity, living a sedentary lifestyle increase the likelihood of developing HF (Meyer, 2001; Ringen, Engh, Birkenaes, Dieset et al., 2014; Shulman, Miller, Misher & Tentler, 2014). In addition, research has also shown that the risk of developing HF is under-recognised and under-recorded in people with a SMI (McLean, Langan, Martin, Guthrie et al., 2014; Smith et al., 2013) and that even when physical health problems are identified, people living with a SMI have a lower chance of receiving the appropriate care for HF (Jorgensen, Mainz, Egstrup & Johnsen 2017; Mitchell, Lord & Malone, 2012).

People living with a SMI and HF are likely to be required to commit to a complex treatment plan and strict self-care maintenance behaviours (Brannstrom, Ekman, Norberg, Bowan et al., 2006; Levensky, O'Donohue & William, 2006). They are likely to have been prescribed a range of medications for their illnesses requiring adherence on a daily basis. In addition, they may be required to attend regular clinic appointments, and they may have been advised to engage in some form of exercise, stop smoking and change their dietary habits. Making these changes is likely to require significant lifestyle changes, to acquire good self-care habits and to implement multiple adaptive and coping behaviours (Gallacher, May, Montori & Mair, 2011; Riegel, Lee & Dickson, 2011; Roe, Yanos & Lysaker, 2006) and individuals may struggle to maintain their treatment regimen. Therefore non-adherence is an important concern (Ho, Bryson & Rumsfeld, 2009) as this compromises the effectiveness of the available treatment, increases risk of relapse, interferes with recovery, can lead to hospitalisation and in many cases can lead to death (De las Cuevas, Penate & Cabrera,

2016; Levensky & O'Donohue, 2006; Owen-Smith, Stewart, Green, Ahmedani et al., 2016). Research has shown that factors such as patients' attitudes and beliefs about their illness, levels of depression and anxiety, symptom severity, access to appropriate support from family and the healthcare system, and socioeconomic deprivation impact on adherence (Graven & Grant, 2013; Riegel, Moser, Anker, Appel et al., 2009; Roe et al., 2006; Velligan, Weiden, Sajatovic, Scott et al., 2009).

People with a SMI have been found to struggle to cope with their illness, and to adhere to their treatment regimen (Gilmer, Dolder, Lacro, Folsom et al., 2004; Haddad, Brain & Scott, 2014; Nelson, Graham, Lindsey & Rasu, 2011; Owen-Smith et al., 2016; Roe et al., 2006). People with HF have also been found to struggle (Chin & Goldman, 1997; Cole, Norman, Weatherby et al., 2006). It is likely, then, that those with both a SMI and HF may be likely to struggle with a more complex and demanding treatment plan. However, little is known about the experiences of people living with a SMI and HF. It may be that some of the factors highlighted above impact someone living with a SMI and HF. It may be that there are factors that are important for this population that have not yet been highlighted. It is important to identify and understand these factors, so that supports and treatments can be put in place to improve the quality of care and the quality of life for these patients.

Qualitative research, in particular, Interpretative Phenomenological Analysis (IPA), is particularly appropriate to explore the experiences of patients with SMI and HF, as it explores the idiographic subjective experiences of individuals, how they ascribe meaning to their experiences and how they make sense of their world (Biggerstaff & Thompson, 2008; Holland, Thomson & Henderson, 2006).

### *Aim*

The aim of this study is to describe the experience of people with a SMI and HF. Specifically, to explore participants' understanding of their illnesses and the factors influencing how they manage their illnesses.

## **Method**

### *Design*

The present study adopted a qualitative design to enable the exploration of the experience of living with SMI and HF. IPA focuses on meaning-making and is

concerned with the detailed examination of personal experiences, perceptions, and views of the participants (Smith, Flowers & Larkin, 2009). With its theoretical foundations in phenomenology, hermeneutics and idiography, IPA focuses on the world as it is being experienced by the individual. IPA attempts to analyse, interpret and then present an account of the ways in which people experience specific and important events in their lives (Kaselionyte & Gumley, 2017; Smith et al., 2009).

### *Interviews*

The aim of the interview was for the interaction to be defined more by the person rather than researcher-led assumptions or questions, in order to implement IPA's inductive epistemology (Smith et al., 2009). Semi-structured interviews (Appendix 5) were chosen for their tendency to produce rich data. They provide the participants the opportunity to freely tell their stories, reflect on their experiences, and introduce novel issues (Kaselionyte & Gumley, 2018; Smith et al., 2009). The content of the semi-structured interview was developed in collaboration with the researcher's field supervisor, a clinical psychologist, working with patients who have heart problems and significant mental health difficulties. The duration of interviews ranged from 45-65 minutes (average 60 minutes). All interviews were recorded before being transcribed verbatim and anonymised by the researcher, with identifying information removed.

### *Procedure*

Prior to commencing recruitment, ethical approval was obtained from the East of Scotland Research Ethics Committee (Appendix 6-17/ES/0125) Research and Development Management Approval was obtained for NHS GGC (Appendix 7-GN17MH446), and Caldicott guardian approval from NHS GGC was obtained (Appendix 8). Recruitment took place between October 2017 and March 2018. There were two methods of recruitment. The first method was via consultation with staff from the Cardiology teams throughout NHSGGC. HF nurses, pharmacists and cardiologists were provided with standard information leaflets (Appendix 9) and were asked to consider, in collaboration with researcher, patients on their caseload who may be eligible for inclusion in the study. The second method involved data linkage between two independent datasets maintained by Cardiology services and mental health services in NHSGGC. Individual patient CHI numbers provided by the HF

team were cross-matched with the Psychosis Clinical Information System (PysCIS database, NHS GGC). Overlapping CHI numbers were given to researcher, who then contacted the clinical team to discuss eligibility.

If a potential participant met the eligibility criteria and was judged by the clinical team as stable, the potential participant's next appointment date was discussed and it was agreed that the clinician would provide the participant the Participant Information Sheet (PIS) (Appendix 10) and ask the potential participant if they agreed to the researcher contacting them. When feasible, the researcher was available during clinics to offer potential participants the opportunity to discuss or ask questions about the study. Potential participants who agreed were contacted via telephone at least 24 hours following their appointment. Further information was provided about the study and a pre-screen was conducted to determine current mental state and overall wellbeing, to determine if the person was still eligible to go ahead with the study. They were asked to report on their mental health diagnosis (as was not clear in medical notes). They were informed that a letter would be sent to their GP and nurse/cardiologist (Appendix 11) to make them aware that their patient was participating in the study. Following this, and if judged by researcher to be physically and mentally well, an interview was arranged. All interviews took place at the potential participant's GP surgery. Written informed consent was obtained prior to commencing the interviews (Appendix 12).

### *Participants*

Participants were English speaking, over the age of 18, who were diagnosed and receiving treatment for HF and had a diagnosis of schizophrenia, psychosis or bipolar disorder. They were prescribed either a mood stabiliser (lithium) and/or an anti-psychotic (e.g. clozapine, olanzapine, risperidone, quetiapine). They were judged to be physically and mentally well enough to participate (based on clinical judgement of the clinical team in the first instance, and then by researcher's clinical judgement at initial telephone contact, and on day of interview) with no other medical comorbidity. Potential participants were excluded if they had a diagnosed learning disability, were judged to lack capacity, or were currently unwell (e.g. psychiatric hospitalisation within the last 6 months). Those who were not competent in understanding questions in English were also excluded.

A total of 11 potential participants were identified using the recruitment methods. Four were judged by the clinical team to be too unwell (one receiving palliative care, two had recent hospitalisations, one judged to be too anxious) to participate. Two people did not attend appointments. Finally, two people were judged to lack capacity and could not give informed consent. Three individuals gave informed and written consent to participate in the current study. A summary of participant characteristics is shown in Table 1 below. Pseudonyms were assigned to maintain anonymity.

According to Pietkiewicz and Smith (2014), there is no rule regarding how many participants should be included in an IPA study. They highlighted that the number should depend on: the depth of analysis of a single case study; the richness of the individual cases; how the researcher wants to compare or contrast single cases; and the pragmatic restrictions (such as time constraints or access to participants) one is working under. Braun and Clarke (2013) have suggested that sample sizes should be adequate to ensure there are enough data to develop a rich story yet not too much that time and resources limit a deeper analysis of the data. Similarly, Smith et al., (2009) highlight that sample size is contextual in IPA and must be considered on a study-by-study basis. Hefferon and Gil-Rodriguez (2011) have said that given the idiographic focus in IPA, “less is more” in terms of sample size and that fewer participants examined at a greater depth is always preferable to a broader, shallow and simply descriptive analysis of many individuals.

Table 1: Participants’ Demographic Information

<b>Participant</b>	<b>Jack</b>	<b>Mary</b>	<b>Jane</b>
<b>Age (years)</b>	48	56	51
<b>Gender</b>	Male	Female	Female
<b>Ethnicity</b>	White Scottish	White Scottish	White Scottish
<b>SMI diagnosis (medication)</b>	Schizophrenia (clozapine)	Psychosis (clozapine)	Bipolar disorder (lithium)
<b>Years since HF diagnosis</b>	1yr 2 months	2 years	10 years
<b>Employment status</b>	Unemployed	Unemployed	Unemployed
<b>Marital status</b>	Single	Single	Single

### *Data analysis*

IPA was used to analyse the transcripts, following a number of recognised stages (Smith et al., 2009). Firstly, each transcript was read repeatedly, allowing the researcher to immerse herself and become familiar with the account. A case study for each transcript was written, with the intent of trying to understand and to tell the participant's story, staying as close to the participant's language as possible. Next, exploratory descriptive, linguistic and conceptual codes were made on the right hand margin of the transcript. Following this, emergent themes were then developed on the left hand side of the transcript by identifying patterns between these exploratory codes (Appendix 13). Connections and patterns across the emergent themes were then identified within the transcript (Idiography). The researcher actively sought to explore aspects of the transcript that had not been included in preliminary thematic codes. In reviewing these 'unused' data existing themes were elaborated and new themes constructed ensuring full saturation of the available data within each transcript. This process was repeated for each individual case to ensure a thorough analysis of the data. Individualised themes were compared to the original case studies (see Appendix 14 for example of case study) to ensure commitment to idiographic analysis. The researcher asked themselves to what extent would participants agree that these case summaries and themes were accurate to their experiences and language. Once themes had been identified in individual transcripts, overarching superordinate and subordinate themes were identified across all transcripts by considering patterns, similarities and differences between accounts (Appendix 15). All themes were labelled using participants own words to ensure analysis stayed close to participants language. A secondary rater (research supervisor) independently rated a sample of the transcripts, and discussions of emergent themes identified a good level of concordance.

### *Researcher reflexivity*

The researcher has a central role in the process of IPA. In particular, it is important to consider how the researcher's beliefs, assumptions and experiences may influence the interpretation of the participant's account. In order to increase awareness of potential sources of bias and the emotional reactions evoked by interview content, the researcher completed a reflective log. This enabled the process of 'bracketing'

perspectives, ideas and expectations throughout the research process (Smith et al., 2009). Supervision was also used as a space to reflect on the emotional impact of the interviews and to facilitate the awareness of possible assumptions or sources of bias. Toma (2000) recommends attempting to get as close to the participant's experience as possible in order to enhance understanding of this experience. Research supervision was used to help test validity and develop the coherence and plausibility of the interpretation.

## Results

The analysis resulted in the development of three interrelated superordinate themes (Table 2). For the purpose of transparency within the analysis these themes are presented with participant narratives and substantiating excerpts.

Table 2: Superordinate and Subordinate themes

Superordinate	Subordinate
"It was just so stressful"	Loss/grief Being so ill Diagnosis Cause Positioning the illnesses
"You're not the same person that you were"	Emotional consequences Change to lifestyle Managing treatment plan
"I don't know what I'd do without them"	Lack of support Talking helps

Three participants provided insight into what it is like to live with a severe mental illness and heart failure. They reflected on difficult life changing experiences, and how they believed that these experiences contributed to their illnesses. They highlighted the impact these illnesses have had on their lives, for example, the

emotional consequences, changes and limitations, and the role of other people for support.

### **“It was just so stressful”**

All participants reflected on their experiences of being ill. They all experienced a life changing loss that triggered significant mental health difficulties. They all believed that this experience might have, in some way, contributed to the development of HF, particularly in relation to the extreme levels of stress they experienced. Getting a diagnosis of HF was “a bit of a shock” as they had had no previous knowledge or issues related to their heart. They all tried to make sense of what caused the HF, two believing they may have caused it. Finally, they all highlighted struggling with the emotional consequences of being so ill.

### **“When it stopped, it stopped dead” – Loss/grief**

When describing experiences leading up to the development of heart failure all participants reflected on their experience of stressful life events. These events involved experiences of significant loss and grief and tended to make sense of the emergence of their heart failure in this context. When Jack’s mother died he “*took it quite bad*” (Jack, 5.124):

*“When my mother died, I took it quite bad so I did...it made me really depressed, I went into a wee depression yeah...I think it was just cause of the way she died...I think I was just under a lot of stress an that yeah, yeah a lot of things sorta just ganged up on me... “I just locked myself in my room an that, I never even came out” (Jack, 29.713-716).*

Mary had suddenly lost her job due to an accident:

*“It was a good job, I enjoyed it, so when it stopped, it stopped dead you know, and I couldn’t walk, you know, and I think that’s when I went into a deep depression” (Mary, 5.125-126).*

Jane struggled with the unexpected loss of her father:

*“When I lost my Dad it just tore the heart out of everyone...that was just horrible...I just took on too much and that’s how I became to have mental*



*illness...I took a breakdown and I was hospitalised for three and a half months” (Jane, 7.192-193).*

#### “I can’t go on like this” – Being so ill

Before being taken into hospital and diagnosed with HF, all participants had been going through what could be described as a crisis, and these experiences seemed to be important in participants making sense of the timing of their HF. Mary had recently moved house, and had started to hear voices.

*“I’d just moved into a new house {okay} and the whole upheaval of moving, I think it took a lot out of me and when I moved into the house I started to hear voices {okay} and I became frightened because I thought the voices were real...and it just got to the stage, it must’ve been it just got all too much and I ended up having a heart attack” (Mary, 2.41-44).*

In addition to still grieving the loss of his mother, Jack had also been struggling with his physical health for a long time:

*“I had this persistent cough for a long while couldn’t get rid of it...and then one day I woke up I was very badly swollen...my legs and feet were all inflated an that and I could barely breath...I went down to the hospital, the accident and emergency and I got taken in” (Jack, 1.5-10).*

Jane had been suffering with asthma for months. She had been to hospital on two previous occasions. On the third occasion she was diagnosed with HF. Before being given the diagnosis, she described feeling like she couldn’t go on:

*“I thought oh my God please I can’t go on like this, and at that time I was annoyed and I thought, I need to know what’s going on I’ve had enough I need to know what’s going on I’m gonna end up, it’s gonna kill me. There’s nothing worse than when you’re fighting to breathe and you think your hearts just gonna stop...” (Jane, 3.62-64).*

#### “It was a bit of a shock right enough” – Diagnosis

The diagnosis of HF was unexpected, and a significant life-changing event associated with a range of intense emotions. When given the diagnosis of HF, and when they realised the severity of their illness, the main emotion described was fear:

*Jack: It was a bit of a fright yeah...you've got heart failure its like, it's frightening yes (Jack, 2.27).*

*Mary: "I got such a fright with the heart attack, and I believe the doctor saved me, and next time he might not have been able to help me" (Mary, 17.435).*

As mentioned above, Jane spent months thinking she had bad asthma. When she finally received a diagnosis of HF and started on appropriate medication she described initially feeling relief:

*"I got my diagnosis the third time, and what a relief, such a relief to get diagnosis and get put on medication...it was like a wonder pill, I was like oh my God, it was just so...my breathing, it was an instant relief, just an instant relief" (Jane, 3.68-69).*

It was only after Jane got discharged back home when the reality of her diagnosis sank in:

*"I thought oh god I've got a heart condition, that's, that's scary, I've got a heart that's impaired, that's not working properly and I, I could die, and, took me really, to get my head around" (Jane, 3.87-88).*

#### "I brought it all on myself" – Cause

There was a process of trying to come to terms with the diagnosis, and trying to determine what may have caused their HF. On three occasions, Mary explained that she believed her levels of distress associated with hearing voices caused her HF:

*"I didn't realise it at the time what was happening you know {okay} and this started because I was so frightened. I actually brought the heart attack on myself, you know" (Mary, 1.17-18).*

Jack gave the impression that he was still searching for an answer to what caused his HF. He highlighted that *"it runs in the family right enough"*. Also, that side effects of anti-psychotics was one of the *"theories"* (Jack, 8.187) suggested to *"have attributed*

*to the heart failure*” (Jack, 8.187). He also expressed on two occasions that he maybe “*worried too much and brought it on*” (Jack, 6.150). On the other hand, Jack talked about eating healthy and that he “*hadn’t had anything that should cause heart failure*”, and therefore, he gave the impression that he was still actively making sense of “*why I had to come down with it*” (Jack, 6.39).

#### “I don’t think one affects the other” – Positioning the illnesses

There were important differences in how the participants related their experiences of mental and physical health difficulties. This could, in part, be explained by timing of the difficulties. Mary believed that her difficulties had “*been building up*” (Mary, 4.96), and that the fear she experienced of hearing voices “*brought on*” (Mary, 1.18) a heart attack and subsequent diagnosis of HF. The two events, hearing voices and a heart attack, occurred close in time.

Jack and Jane’s experiences occurred at different times in their lives. The onset of their mental health difficulties was in their 20’s, and HF occurred in their 40’s. Jane explained that both conditions had “*definitely affected my life*”. She described living with HF to be “*very debilitating*” but that currently her mental health was “*much better now*” (Jane, 17.478).

Jack offered a lot of information and insight into his HF, however, when asked about his mental health difficulties, he replied, “*I don’t like talking about it*” (Jack, 7.75). He described embarrassment when talking to others about his feelings “*I’m a really private person*” (Jack, 31.769) and that he didn’t like the “*stigma of going to see psychiatrists and psychologists*” (Jack, 32.812). He also explained that he didn’t feel that “*one affects the other*” (Jack, 15.76) in relation to physical and mental health. However, as mentioned above, when trying to determine the cause of his HF, he did make links with his antipsychotic medication and also between how stressed and depressed he had been feeling before he was diagnosed with HF.

#### **“You’re not the same person that you were”**

Participants described many changes to their lives as a consequence of their illnesses. They described fears, worries, uncertainty about the future, struggles with managing their treatment plan, and important lifestyle changes, for example, changes to diet and

exercise, and not going out as much as they used to. They all described feeling limited or restricted by their illnesses.

#### “I worry about this and I worry about that” - Emotional consequences

Anxiety, and a sense of feeling daunted by their illnesses was apparent for the participants. Much of this anxiety was related to having a heart attack or dying young:

*Jack: “I’m just worried in case (pause) maybe doing too much or something like that an {okay} might bring on a heart attack or that (laughs) (Jack, 19.480-481).*

*Jane: “I try not to let it get me down, but eh, but it does, it scares me, and I’m scared in case I die young from it, and that scares me sometimes (pause) I try not to think like that but...I do really worry sometimes, I do really worry (Jane, 4.110-112).*

For Mary, rather than worry or fear about something happening physically, she was trying to cope with hearing voices on a daily basis, “*the problem is the voices, I still hear those voices*” (Mary, 18.451) which she found “*scary, very scary*” (Mary, 19.478) and it was these voices that she saw as causal to her HF.

#### “I don’t venture out too much now” – Changes to lifestyle

These intense worries impacted the participants’ quality of life:

*Jack: “I think coz I’m worried in case something happens to me yeah...yeah even walking down a flight of stairs I’m always thinking about things like that an so I don’t come out so much now an that, try to stay in quite a lot now, I don’t venture out too much now yeah” (Jack, 19.459-463).*

Jane described changes as a result of her illnesses as life restricting:

*“It’s (pause) it’s life restricting (pause). I used to love walking (pause) can’t do that anymore...” (Jane, 4.109).*

Jane also described a desire to do more as she felt this would help with her health, but felt worried about something happening:

*“I would love to eh I really would but eh just at the minute I worry in case I do exercise now and something happens” (Jane, 15.443).*

For Mary, she used to feel very capable and organised, and now felt dependant on everything. These feelings impacted her life, and given the number of pauses she took to explain this, possibly highlighted the emotional significance for her:

*Mary: “ I used to be an avid reader but I can barely be bothered to read anything you know...I don’t have the concentration...I used to be quite an organised person ehh, very capable but I’ve went from one extreme to the other whereas I’m dependant on everything, you know”.*

***Interviewer: “And how does that make you feel?”***

*Mary: “Pretty crummy (laugh) it’s the only way I can describe it, ehh, you’re not the person that you were (pause) well I’m not (pause) I used to be out and about, good source of life and (pause) had a good job and I lost everything you know (pause) feel as if I’ve lost ma identity...(Mary, 15.381-390).*

#### “It’s a bit of a nuisance actually” – Managing treatment plan

All three participants commented on healthcare staff and how they “*never says what I shouldn’t do or what I should do...eh they just eh, keep onto my medication an that*” (Jack, 4.93). In relation to medication, they all talked about the number of medications they are required to take and how they sometimes forget to take them:

*Jane: “I make sure to take my medication regularly which I do do, there’s a couple of days here or there I won’t, I’ll miss a dose but I think that’s quite normal I know I shouldn’t but I do” (Jane, 13.385-386).*

For Mary, she was finding managing her medications difficult, to the extent she required support from the pharmacy:

*Mary: “Well at first I was getting it all mixed up, then they organised me a blister pack and that makes it a lot easier ya know”.*

***Interviewer: “Okay, who organised that for you?”***

*Mary: “The chemist”.*

***Interviewer: “And how was that for you?”***

*Mary: “Good, definitely a lot better (pause) coz I was getting all my medication at the same time and I was running out, and I was forgetting to order something and I didn’t realise I was so low in something and I would run out” (Mary, 13.329-345).*

Jack also forgot to take his medication sometimes and described his medication plan as *“a bit of a nuisance actually”* (Jack, 12.293). Unlike the other participants, Jack discussed issues he had with medications. He felt anxiety around taking medication because he didn’t like tablets that *“mucks around with the heart”* (Jack, 22.536), and said that he’d rather not know what they do and just take them.

### **“I don’t know what I’d do without them” – Role of others**

The value of others was something that was highlighted by all three participants. Unfortunately for Jack, his mother was the only person in his life so when she died it *“took the fun out of everything”*, (Jack, 29.735) and he didn’t have anyone else. For Mary and Jane, they had family who helped with their mood, alleviating worries and providing reassurance. For the most part, support from health care staff was viewed as positive, however, they all experienced, to some degree, a lack of support, a lack of understanding, and a lack of shared decision making about their care.

### **“Nobody ever told me what to do” – Lack of support**

All three participants described the support they received from healthcare professionals. For the most part, participants described the care and support as being positive, however, all three also described a lack of adequate support or information at some point or another during their time involved with services. Jane was positive about her support from cardiac professionals. She also described getting taken care of when she was in psychiatric inpatient care but then *“they decide she’s fine to get out”* (Jane, 8.236) and that *“you come out and it’s just boom”* (Jane, 9.242). She explained that it’s *“absolutely crazy because that’s when the depression starts”* (Jane, 8.236). These statements suggested that Jane didn’t feel she received an appropriate level of support following discharge. Her statement *“they decide she’s fine to get out”* was striking, implying a lack of involvement in decision-making.

As mentioned earlier, in relation to medication, both Mary and Jack described not being given enough information about how to take their medication. Mary explained, “*nobody ever told me what to do*” (Mary, 13.319). Jack described feelings related to anxiety regarding information on medication, explaining that he felt it was “*irresponsible*” to prescribe medication without giving out information on side effects. When asked if he’d been given information he said that a “*nurse did run over it with me*” (Jack, 14.338), however, the use of the word “*run*” suggests he may have felt that the information was given too quickly, and that maybe he feels that not enough time was spent going through this information. Jack highlighted that one of the “*avenues*” that healthcare professionals had considered was that the anti-psychotic he had been taking for a long time may have caused his HF, thus, it was understandable that he may have felt that they “*could better explain that type of medication*” and why his concern about side effects “*puts the fear of death in you*” (Jack, 9.234).

#### “I’ll always be indebted to my mum” – Talking helps

Both Mary and Jane described the importance of having others around to support them, both practically and emotionally. It was helpful to have professionals to talk to and provide reassurance, “*I could talk to her (CPN) about anything and she was such a good listener and she reassured me*” (Jane, 9.257). Mary also had family who visited and spent time with her:

*“That’s nice that somebody’s taken the time out to do that you know, as I mighta been sitting in that day, feeling low, and he’s cheered me up (Mary, 23.571-572).*

In contrast with Mary and Jane, Jack described himself as a “*very private person*” (Jack, 10.246), and that he didn’t “*find it easy to talk to people*” (Jack, 10.239). He also felt that he didn’t see “*how anybody else would be able to help me in that way*” (Jack, 18.437). Jack explained that he didn’t have any other family, that he only had his mother, and that he took his mother’s death “*quite bad*” (Jack, 5.124).

## **Discussion**

This qualitative study explored the experiences of people living with a severe mental illness and heart failure. Specifically, it examined how they made sense of what it was

like to live with two severe illnesses, what they find difficult about their illnesses, and what helps them to cope with and manage their illnesses. Three main themes were identified from the participants' accounts. These themes were focused on the experience and stresses associated with being ill, changes and adjustments that were made as a result of being ill, and the role of others in helping to manage their illnesses. While these three themes are presented separately, they were inter-related, particularly the emotions experienced by participants across all three themes.

All three individuals in this study had experienced a significant loss in their life. They all identified being unable to cope with the intense emotions and distress, therefore, making them vulnerable to a significant period of mental ill health. They all attempted to process and make sense of these experiences. One participant believed her mental ill health caused her HF. For the other two participants, they did not explicitly link their mental ill health and physical ill health. However, in the process of trying to make sense of why they developed HF, both had questioned whether extreme levels of stress could cause the onset of HF. As such, for these participants, the onset or development of their HF may best be understood in the context of their experience of significant life events and associated levels of distress.

Receiving a diagnosis of HF was understandably frightening for all three participants. The worry and fear associated with the uncertainty of their cardiac symptoms was alleviated somewhat by the diagnosis of HF. However, the anxiety and fear of something happening in the future was a current and persistent characteristic for all participants. For example, a fear of dying young, constant worrying about having a heart attack, or a fear of the voices returning. Related to this were the behavioural changes that all three participants described. They were conscious of the fact that in some way, the change was associated with low mood or anxiety, rather than physical limitations related to their HF. They highlighted not feeling motivated to do things, or purposefully avoiding things they used to do, for fear of something happening, whether it be a physical event, such as a heart attack, or an escalation in voice hearing. There was, however, a desire to do more, to get back to doing some of the things they used to do and enjoy. This finding echoes results by Thornhill, Lyons, Nouwen and Lip (2008), which explored people's experiences of living with HF and also found that people expressed a desire to get back to doing things they enjoy doing.



The study highlighted the value that participants placed on others, both professionals and family members, to support them with recovery and adjusting to their illnesses. The findings provided specific examples of what participants needed and valued from other people. Firstly, practical support was highlighted, in particular, support with medication management. All three participants described difficulties with this and one participant highlighted that support from a pharmacist resolved difficulties with managing medication. This finding supports research focused on the role of the pharmacist for improving treatment adherence (Murray, Young, Hope, Tu et al., 2007; Parajuli, Franzon, McKinnon, Shakib et al., 2017). Secondly, an awareness of psychological distress and offering emotional support was identified as valuable. This helped to alleviate emotional distress and worries, provide reassurance and lift mood. Therefore, provision of psychological support may help people adapt to and manage their health better. Research has shown that failure to do so can result in poorer outcomes and faster disease progression (de Ridder, Geenan, Kuijer & van Middendorp, 2008).

What was apparent for all three participants was how they provided a rich insight into their lives and their experiences of two severe illnesses, including how they conveyed the day-to-day struggles that they faced. What emerged from these accounts was a portrayal of resilience, determination and an ability to cope with significant life changes. Unlike previous research that suggests that people with HF and people with a SMI struggle to adhere to their treatment plan (Cole et al., 2006; Gilmer et al., 2004; Owen-Smith et al., 2016), the participants in this study appeared to meet the challenges of managing the complex demands of managing two difficult and life changing conditions. They were also attending their routine appointments with both physical and mental health clinicians. They did explain some lifestyle changes, such as avoiding going out, however, they all expressed a desire to do more and they did not engage in many of the poor lifestyle behaviours that research suggests people with a SMI are more likely to engage with (Meyer, 2001; Ringen et al., 2014; Shulman et al., 2014).

#### *Methodological Strengths and limitations*

We aimed to identify a homogeneous sample of individuals with an SMI who had experienced heart failure and were under follow-up from Cardiology services.

Recruitment efforts were significant in terms of screening caseloads of busy cardiology clinicians and also undertaking an independent data linkage. These data had not previously been linked and a number of important governance permissions needed to be established in order to receive permission from the Caldicott Guardian. Our final sample of three participants is small but within guidelines for IPA. As a result we ensured that our analytical approach had a depth of commitment to the idiographic nature of IPA through the development of within transcript coding and individual case studies. During the coding process we actively sought to identify data that had not been captured during the initial coding processes and this enabled us to challenge and elaborate emerging codes and themes. Only when we had fully saturated data within an individual transcript did we seek to compare and contrast across transcripts. Although a general limitation of qualitative methods is the influence of subjectivity, interpretation and bias, we ensured that the researcher completed a reflective log throughout the process and received regular supervision where their own assumptions and interpretations of the data were actively explored and contested. In addition, a check of validity was conducted by the research supervisor. It is important to note that the inclusion criteria for the study may have influenced recruiting individuals who were successfully negotiating two complex conditions, therefore, excluding individuals who may be finding this difficult.

### *Implications for clinical practice*

The study demonstrated that participants were managing the demands of two severe illnesses and that participants were able to provide a good insight into their health and into the care they received from services. They were able to identify gaps in service provision that could better equip them with the knowledge and skills to manage their physical and mental health needs and support them to achieve a healthier and more fulfilling lifestyle. For example, extra support with medication, guidance on how much exercise participants can safely do, and emotional support. By including service users in the content design and delivery of a package of care, it could help to ensure that people managing two severe illnesses are receiving the appropriate care. It may also encourage better self-care behaviours. Research suggests that if patients are supported to manage medication and supported with self-care behaviours, they are better able to manage their illnesses (Koshman et al., 2008; Parajuli et al., 2017; Riegel et al., 2011).

There is an increasing evidence base that focuses on the relationship between mental and physical health, in particular, how the current NHS system identifies and provides access to appropriate treatment for people living with both physical and mental health needs (The King's Fund; Attar, Johansen, Valentin, Aagaard et al., 2017; McLean et al., 2013; Smith et al., 2013). This study highlighted the disconnection between physical and mental health care needs. For example, this study originally aimed to recruit through liaising with the cardiac teams. However, clarifying a mental health diagnosis from physical health notes was difficult, for example, the anti-psychotic medication, clozapine, is not routinely recorded in physical health notes. Often, nursing staff lacked information regarding a mental health diagnosis. As a result, data linkage was required to try to overcome this issue. The significant effort required to recruit participants highlighted a lack of integration between physical and mental health care, and supports and strengthens current health specifications and drivers for integrating physical and mental health care (The King's Fund).

#### *Future research*

Qualitative methods such as IPA can play an important role in uncovering important experiences that contribute to how people navigate their pathway through the NHS. Understanding these experiences have a powerful role to play in designing services that are focussed on and responsive to users' mental and physical health needs. Recruitment highlighted a lack of integration between mental health and physical health services and the impact of this lack of integration was evident in the experiences and meanings identified in this study. Further research broadening the scope into other cardiovascular problems is important, incorporating the views of those with a lived experience of both SMI and cardiovascular problems is merited. Research focussing on a broader range of perspectives, at different points in the care pathway in both mental and cardiovascular services could be valuable in helping improve services design, for example, in the content design and delivery of self-management interventions. In addition, participants in this study described important emotional needs in relation to adaptation to their HF and further research is merited to explore whether these needs could be addressed by psychological interventions to enhance recovery and adaptation. Finally, given the inclusion and exclusion criteria, people functioning at a lower level were likely to have been excluded from this study. Future research should attempt to engage this population, not only to understand their

lived experiences, but ideally, also as co-producers and collaborators in the research and design of service delivery.

### *Conclusion*

This is the first study of its kind that we are aware of to examine the experiences of people living with both a severe mental illness and heart failure. The results highlighted difficult life experiences for every participant, and offered insight into the impact of these experiences. It demonstrated a process of trying to make sense of and come to terms with these experiences. Change was apparent for all participants, specifically, adhering to a lot of medication, not feeling able to do things they used to do, and having to live with, on a daily basis, the fear and worry that is brought about by living with a SMI and HF. The study highlighted the role of others, suggesting times when the level of care may have fallen short, and the type of support, mainly emotional support, that participants found to be most helpful. Finally, the study demonstrated that participants were able offer a good insight into their experiences, show good compliance, resilience and determination in the face of day-to-day challenges associated with two severe illnesses.

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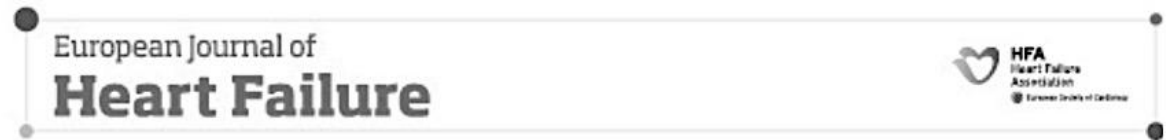
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## APPENDICES

### Appendix 1 – Submission requirements for European Journal of Heart Failure



#### Author Guidelines

##### REQUIRED FORMS

*European Journal of Heart Failure* requests that all authors complete:

An ICMJE Conflicts of Interest disclosure form

Author Contribution form

Please note that these forms are here for reference, and authors will have the opportunity to complete versions of these forms in the online submissions system.

##### INTRODUCTION

Thank you for your interest in *European Journal of Heart Failure*. Please consult the following instructions for help in preparing your manuscript, and feel free to contact us with any questions. To ensure fast peer review and publication, manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review. We look forward to your submission.

##### AIMS AND SCOPE

The *European Journal of Heart Failure* is the international journal of the Heart Failure Association of the European Society of Cardiology dedicated to the advancement of knowledge in the field of heart failure. The journal publishes reviews and editorials in order to improve the understanding, prevention, investigation and treatment of heart failure. Molecular and cellular biology, pathology, physiology, electrophysiology, pharmacology, as well as the clinical, social and population sciences all form part of the discipline that is heart failure. Accordingly, submission of manuscripts on basic, clinical and population sciences is invited. Original contributions on nursing, care of the elderly, primary care, health economics and other specialist fields related to heart failure are also welcome.

##### HEART NETWORK

The *European Journal of Heart Failure* participates in the HEART Network which is a network of Editors from most cardiovascular journals. Information is exchanged between Editors on a regular basis. The network has recently approved a common ethics standard.

Its purpose is to ensure transparency and honesty in the scientific process that promotes ethical conduct in performance and publication of research.

The following will be considered as parts of this process:

- a. Disclosure of potential conflicts of interest for all involved in the performance of research and in the evaluation and publication process of a manuscript. Relevant relationships with commercial interests should be disclosed according to the guidelines of the journal's sponsoring society, or, when no such guidelines exist, according to those of the AHA, ACC, or ESC.
- b. Establish thorough review processes particularly alert to discovering scientific fraud and data falsification, redundant or duplicate publication, and plagiarism, and to adopt a uniform standard of dealing with authors guilty of fraudulent practices.
- c. To maintain confidentiality and embargos where appropriate.
- d. To create uniform criteria to establish authorship. To qualify for authorship, individuals must have made substantial contributions to the intellectual content of the paper in at least one of the following areas: conceived and designed the research, acquired the data, analysed and interpreted the data, performed statistical analysis, handled funding and supervision, drafted the manuscript, or made critical revision of the manuscript for important intellectual content. Authors must give final approval of the version to be submitted and any revised version to be published. For multi-centre trials, individuals who accept direct responsibility for the manuscript should fully meet the criteria for authorship defined above and contributors not meeting these criteria should be acknowledged.
- e. Avoidance of false claims of ownership, priority, by attention to previous publications.

f. Avoidance of excessive claims of benefits of a product/technique, in the publication as well as with news media.

g. Noting compliance with institutional review board requirements and, when appropriate, approved laboratory procedures for animal research, and that the research conforms to the ethical standards of the *Declaration of Helsinki*, the *Geneva Declaration*, the *Belmont Report*, and *Good Clinical Practices* from the FDA, and the submission conforms to the *International Committee of Medical Journal Editors (ICMJE): Uniform Requirements for Manuscripts Submitted to Biomedical Journals: writing and editing for biomedical publication* (Haematologica 2005; 89:264).

## **PRE-SUBMISSION**

### **1. Editorial Review and Acceptance**

The acceptance criteria for all papers are the quality and originality of the research and its significance to our readership. Except where otherwise stated, manuscripts are double-blind peer reviewed by two anonymous reviewers and the Editor. Final acceptance or rejection rests with the Editorial Board, who reserves the right to refuse any material for publication.

Manuscripts should be in a clear, concise and direct style. Where contributions are judged as acceptable for publication on the basis of content, the Editor and the Publisher reserve the right to modify typescripts to eliminate ambiguity and repetition and improve communication between author and reader. If extensive alterations are required, the manuscript will be returned to the author for revision.

### **2. Pre-submission Resources**

#### **2.1. Author Services**

Prior to submission, we encourage you to browse [Wiley's Author Resources site](#), which provides useful information on topics such as preparing your article and digital artwork; publishing ethics; copyright and open access; and how to promote your published work.

#### **2.2. Pre-submission English-language Editing**

Authors for whom English is a second language are advised to consider having their manuscript professionally edited before submission to improve the English, and to ensure the paper is clearly written in standard, scientific English language appropriate to the discipline. This can be undertaken by a service such as the Wiley English Language Editing Service, at <http://wileyeditingservices.com>. Please note that using the Wiley English Language Editing Service does not guarantee that your paper will be accepted by this journal, and all services are paid for and arranged by the author.

### **3. Manuscript Preparation**

#### **3.1. Manuscript Categories and Criteria**

The *European Journal of Heart Failure* accepts the following categories of articles:

##### **Research Articles**

These should not exceed 3500 words (excluding references, tables and figures) and may include up to a maximum of 6 figures and/or tables and up to 30 references. Research articles should be divided into the following sections: (1) Title page, (2) Abstract and up to six Keywords, (3) Introduction, (4) Methods, (5) Results, (6) Discussion, (7) Acknowledgements, (8) Funding, (9) Conflict of interest, (10) References, (11) Figure legends, (12) Appendices, (13) Tables, (14) Figures. The Abstract should be divided into the following sections 'Aims', 'Methods and results' and 'Conclusion'; it should not exceed 250 words.

##### **Reviews**

The *European Journal of Heart Failure* publishes a limited number of scholarly, comprehensive review papers. Reviews should not exceed 3500 words. They should summarise and critically evaluate research in the subject area, and should discuss implications for the future. Reviews have unstructured abstracts with no headings, which should not exceed 250 words and may include up to 45–50 references. Please see below for systematic reviews.

##### **Systematic Reviews**

These reviews should follow the format of research articles (refer to the section, 'Research Articles'). These should be submitted as a research article during the submission process.

##### **Editorials**



All editorials should be limited to 1500 words (excluding references), with a maximum of 15 references. They do not require an abstract and may include one table and/or one figure. In particular, the addition of one figure would be welcome and could add to the understanding and attractiveness of the article. The following different categories of editorials may be considered:

- **Editorial comment.** Written upon invitation by the Editor, it is a comment to a research article and should discuss its results, compare them with the current literature and give a personal interpretation of the study.
- **Viewpoint.** This is a commentary on a topical item. It may be invited or not. When we receive more viewpoints regarding a similar topic they may be gathered under the category of "Different viewpoints" in the index page. However, their labelling will remain "viewpoint" in the title page so that they may be considered alone.
- **Opinion Piece.** This has to be written by one single author and have possibly controversial content and opinions.
- **In the News.** This is a single author comment on recent event or trial.
- **From opinion to evidence.** This is an expert opinion and can be written by multiple authors. It must be based on facts and be evidence based. Differently from the other categories of editorials, it may reach 2000 words and 30 references.

### **Short Reports**

These reports should not exceed 1500 words and should comprise a Background section (≈100 words), Aims (≈50 words), Methods (≈300 words), Results (300 words) and Conclusion (250 words). The editorial team reserves the right to decide which of the tables/figures submitted are necessary. A structured abstract not exceeding 250 words is also required for Internet purposes.

### **Letters to the Editor**

Letters to the Editor may regard comments to an article published in our journal in the previous months. These letters should have a maximum of 3 authors, should not exceed 400 words and have a maximum of 5 references, including one reference to the article that they are about. We may ask for a reply to the authors of the original article and the letter and its reply be published together.

### **Research Letters**

Letters based on original research findings are also allowed. The letter may include up to 1000 words, including a maximum of 8 references, and one figure and/or Table. Research letters should have no abstract and no sub-headings. However, a short description of methods, results and conclusions is required.

### **Case Reports**

These reports should not exceed 1200 words. Case reports should include an unstructured Abstract with no subheadings (not exceeding 100 words), an Introduction, a Description of the case(s) under the heading, 'Case Report' and a Discussion of the findings in the context of current practice.

### **Study Design**

These should not exceed 3500 words (excluding references, tables, and figures) and may include up to a maximum of 6 figures and/or tables and up to 30 references. Study design papers should be divided into the following sections: (1) Title page, (2) Abstract and up to six Keywords, (3) Introduction, (4) Study Design, (5) Discussion, (6) Acknowledgements, (7) Funding, (8) Conflict of Interest, (9) References, (10) Figure legends, (11) Appendices, (12) Tables, (13) Figures. The Abstract should be divided into the following sections 'Aims', 'Methods', and 'Conclusion'; it should not exceed 250 words.

### **Book Reviews**

Book reviews may include up to 800 words, including a maximum of 3 references. They should have no abstract and no sub-headings.

## **3.2. Manuscript Format and Structure**

### **General Format**

Prepare your manuscript text using a Word processing package (save in .doc or .rtf format). Submissions of text in the form of PDF files are not permitted. Manuscripts should be double-spaced, including text, tables, legends and references.

Number each page. Please avoid footnotes; use instead, and as sparingly as possible, notes within brackets. Enter text in the style and order of the journal. Type references in the correct order and style of the journal. Type unjustified, without hyphenation, except for compound words (where two words are joined to form a new word e.g. end-systolic, non-infarcted). Type headings in the style of the journal. Use the TAB key once for paragraph



indents. Where possible use Times New Roman for the text font and Symbol for Greek and special characters. Use the word processing formatting features to indicate bold, italic, Greek, maths, superscript and subscript characters. Clearly identify unusual symbols and Greek letters. Differentiate between the letter O and zero; the letters I and l; and the number 1.

Check the final copy of your paper carefully, as any spelling mistakes and errors may be translated into the typeset version.

### **Style and Spelling**

Oxford English spelling should be used. Authors whose first language is not English are requested to have their manuscripts checked carefully before submission. This will help expedite the review process and avoid confusion.

### **Abbreviations**

Abbreviations of standard SI units of measurement only should be used.

### **Ethics**

*Declaration of Helsinki:* The authors should state their study complies with the *Declaration of Helsinki*, that the locally appointed ethics committee has approved the research protocol and that informed consent has been obtained from the subjects (or their guardians).

*ARRIVE Guidelines:* The contribution of animal research in enabling better health for man and animals is incontrovertible and *EJHF* is committed to the publication of research studies which use animal models, but demands the same rigorous attention to detail as in clinical trials. Failure to describe research methods and to report results appropriately has scientific and ethical implications for the entire research process and the reputation of those involved in it.

Experiments involving animals should be appropriately designed, correctly analysed and then transparently reported, to both increase the validity of the results, and maximise the scientific gain. A minimum amount of relevant information must be included in manuscripts published in this journal to ensure that the methods and results of a study can be reviewed, analysed and repeated. *EJHF* will therefore refer to the *ARRIVE (Animals in Research: Reporting In Vivo Experiments) Guidelines* as the basis for the process of reviewing manuscripts of research involving animals.

These guidelines were generated by The National Centre for the Replacement, Refinement and Reduction of Animals in Research, which is an independent scientific organisation, established by the UK Government, in consultation with scientists, statisticians, journal editors and research funders.

### **DNA Sequences and GenBank Accession Number**

For each and every gene accession number cited in an article, authors should type the accession number in bold, underlined text. Letters in the accession number should always be capitalised. Example: (GenBank accession nos. **AI631510**, **AI631511**, **AI632198** and **BF223228**), a B-cell tumor from a chronic lymphatic leukemia (GenBank accession no. **BE675048**), and a T-cell lymphoma (GenBank accession no. **AA361117**).

## **3.3. Parts of the Manuscript**

### **Title Page**

The title page should include the following: (1) the title, (2) the name(s) of authors, (3) the institution(s) where work was performed, (4) the position, institution and location of all authors, (5) the telephone number, fax number and e-mail address of the corresponding author, (6) the institutional affiliations of the authors (including corporate appointments) should be acknowledged in a footnote, (7) total words count.

### **Abstract and Keywords**

All abstracts may not contain more than 250 words and should be submitted as a separate file. The abstract should be formatted with the following heading: (1) Aims, (2) Methods and Results, (3) Conclusion.

A maximum of six keywords may be submitted.

### **Introduction**

This section should provide a rationale for conducting the study within the context of previous work by other authors.

### **Methods**

This section should be sufficiently detailed to enable repetition of the study by other investigators. If pertinent, the section may be divided into headed subsections. For animal studies, this section should contain a statement that, "The investigation conforms to the *Guide for the Care and Use of Laboratory Animals* published by the US National Institutes of Health (NIH Publication No. 85-23, revised 1985)". Human studies should contain a statement that, "The investigation conforms with the principles outlined in the *Declaration of Helsinki*" (*Br Med J* 1964; **ii**: 177). In addition details of the ethics committee approval procedures and a statement that all subjects gave written informed consent to participate in the study should be included.



## Results

If pertinent, the section may be divided into headed subsections. For presentation of data, figures are preferred to tables. Data should not be duplicated in both figures and tables. Extensive numerical data should be presented in legends to the figures rather than in the main body of text. SI units should be used throughout.

## Discussion

Four manuscript pages should in general be enough to compare and interpret the findings of the study with regard to previous work by (other) authors. This section should also contain 1–4 paragraphs dealing with topics that are beyond the scope of the study. Limitations to the study should also be discussed.

## Figures

### General information about graphics:

- All figures should be submitted as separate files.
- Supply figures at final size widths: **84 mm** (single column), **176 mm** (double column) or **125 mm** (intermediate), and containing all parts.
- Label parts clearly using capital letters (e.g. A, B, C etc.).
- Use sans serif, Type 1/OpenType/TrueType fonts for labels (preferably Arial), and Times (New) Roman if serif fonts are required.
- Ensure all lettering/lines are clear and that photographic images are neither blurred nor fuzzy.
- Ensure that all figures are clearly labelled and match the sequence in the text.
- Submit either PDF/EPS (line art) or TIFF (halftone/photographs) files only.
- PDF/EPS files should be saved with fonts embedded (and with a TIFF preview if possible).
- Black and white photographic images should be supplied as 'grayscale'.
- Colour images should be supplied as RGB (not CMYK).
- For scanned images, the scanning resolution (at final image size, see above for a guide to sizes) should be as follows to ensure adequate reproduction:
  - line art, 600 dpi
  - halftones (including gel photographs), 300 dpi
  - figures containing both halftone and line images, 600 dpi
- All scanned images embedded into other applications should be scanned at the recommended resolutions. (e.g., a scanned image placed embedded in a MS Word or PowerPoint document).
- Multipart figures should be supplied in the final layout in one file. If the parts are supplied separately, the individual parts should be named clearly with labels in the filenames.

To facilitate the production of quality published graphics, we recommend that authors generate their graphics in software packages incorporating either a **Save As** or an **Export** to TIFF/EPS/PDF function (e.g.: Adobe Illustrator, Deneba Canvas, CorelDRAW, Adobe Photoshop). EPS files can be produced from other applications, e.g. PowerPoint, but results can be unpredictable (e.g. fonts and shading may not be converted correctly, lines may go missing, dotted lines may become solid).

If an author has difficulty in creating TIFF/EPS/PDF from their native document, they may provide the original documents in their native formats such as PowerPoint, Word, or Excel file. Our typesetters are able to convert/export the native document files from most applications to a standard format for further processing.

For further details, see the Wiley Electronic Graphics standards and information on [preparing electronic graphics](#).

### Figure Legends

These should be on a separate, numbered page, and grouped under the heading "Legends". Define all symbols and abbreviations used in the figure. Common abbreviations and others in the preceding text should not be redefined in the legend.

### Colour Figures

The European Journal of Heart Failure does not charge for colour figures.

### Tables

Tables should be typed with double spacing, but minimising redundant space, and each should be placed on a separate sheet. Tables should be submitted, wherever possible, in a portrait, as opposed to landscape, layout. Each Table should be numbered in sequence using Arabic numerals. Tables should also have a title above and an explanatory footnote below. All abbreviations used should be defined in the footnote. **NB: tables must be**



**submitted in an editable format, such as Excel or Word, and not embedded as an image or presented as an image file.**

#### **Permissions**

If any figures are to be duplicated from previously published work, written permission must be obtained both from the publisher and the author, and a credit line giving the source added to the relevant figure legend. If text material (250 to 300 words) is to be reproduced from published sources, written permission is required from both publisher and author. For shorter quotations, it is sufficient to add a bibliographic credit. The Letters containing the permission for the reproduction of either text or illustrations must be uploaded with the manuscript files. If you have been unable to obtain permission, please indicate this.

#### **Permission Note**

This should list any material (Figures, Tables and/or large amounts of text) that has been previously published. Permissions from the previous publisher/copyright holder should be provided, or alternatively, if all material is original to this submission, then a word document stating this fact should be uploaded with your submission.

#### **Acknowledgements**

Substantive contributions of individuals should be noted in the Acknowledgements, positioned before the Conflict of Interest statement.

#### **Conflicts of Interest**

All authors must make a formal statement indicating any potential conflicts of interest that might constitute an embarrassment to any of the authors if it were not to be declared and were to emerge after publication. Such conflicts might include, but are not limited to, shareholding in or receipt of a grant or consultancy fee from a company whose product features in the submitted manuscript or which manufactures a competing product. The statement should be positioned before the list of references. If there are no conflicts of interest, please insert the wording, 'Conflicts of Interest: none declared'. *European Journal of Heart Failure* uses the ICMJE Conflicts of Interest disclosure form, and requests that each author submits a completed form along with the submission.

#### **References**

References should be identified in the text by Arabic numerals and numbered in the order cited. All references should be compiled at the end of the article in the Vancouver style, except that ALL authors should be listed.

Complete information should be given for each reference including the title of the article, abbreviated journal title and page numbers.

Personal communications, manuscripts in preparation and other unpublished data should not be cited in the reference list but may be mentioned in parentheses in the text. Authors should get permission from the source to cite unpublished data. Titles of journals should be abbreviated in accordance with *Index Medicus* (see list printed annually in the January issue of *Index Medicus*). If a journal is not listed in *Index Medicus* then its name should be written out in full.

We recommend the use of a tool such as EndNote or Reference Manager for reference management and formatting. EndNote reference styles can be searched for here: <http://www.endnote.com/support/enstyles.asp>. For Reference Manager we recommend using the *European Heart Journal* reference style which can be searched for here: <http://www.refman.com/support/rmstyles.asp>.

#### **Article Citation Example:**

1. Lainchbury JG, Troughton RW, Frampton CM, Yandle TG, Hamid A, Nicholls MG, Richards AM. NTproBNP-guided drug treatment for chronic heart failure: design and methods in the "BATTLESCARRED" trial. *Eur J Heart Fail* 2006; 8:532-538.

If an article has been published online but has not yet been given issue or page numbers please use the Digital Object Identifier (doi) number when referencing the article as in the example below:

2. Asger A, Møller JM, Dagaard PC, Kjær SU, Erik S. Effects of phosphodiesterase-5 inhibition by sildenafil in the pressure overloaded right heart. *Eur J Heart Fail*;doi:10.1016/j.eheart.2008.09.016. Published online ahead of print 12 March 2008.

#### **Chapter Citation Example:**

3. Nichols WW, O'Rourke MF. Aging, high blood pressure and disease in humans. In: Arnold E, ed. McDonald's Blood Flow in Arteries: Theoretical, Experimental and Clinical Principles. 3rd ed. London/Melbourne/Auckland: Lea and Febiger; 1990. p. 398-420.

#### **Website Citation Example:**

4. Panteghini M. Recommendations on use of biochemical markers in acute coronary syndrome: IFCC proposals. eJIFCC 14. <http://www.ifcc.org/ejifcc/vol14no2/1402062003014n.htm> (28 May 2004).;

where the date in parenthesis refers to the access date.

#### **Supporting Information**

Supporting information is not essential to the article but provides greater depth and background and may include tables, figures, videos, datasets, etc. This material should be submitted at the same time as the main manuscript, and will appear online, without editing or typesetting. Guidelines on how to prepare this material and which formats and file sizes are acceptable can be found at <http://authorservices.wiley.com/bauthor/suppmat.asp>.

Please note that the provision of supplementary material is not encouraged as a general rule. It will be assessed critically by reviewers and editors and will only be accepted if it is essential.

### **Statistics**

All manuscripts selected for publication will be reviewed for the appropriateness and accuracy of the statistical methods used and the interpretation of statistical results. All papers submitted should provide in their Methods section a subsection detailing the statistical methods, including the specific method used to summarize the data, the methods used to test their hypothesis testing and (if any) the level of significance used for hypothesis testing.

### **Sources of Funding**

Details of all funding sources for the work in question should be given in a separate section entitled 'Funding'. This should appear before the 'Acknowledgements' section.

The following rules should be followed:

- The sentence should begin: 'This work was supported by ...'
- The full official funding agency name should be given, i.e. 'the National Cancer Institute at the National Institutes of Health' or simply 'National Institutes of Health' not 'NCI' (one of the 27 subinstitutions) or 'NCI at NIH' (full RIN-approved list of UK funding agencies)
- Grant numbers should be complete and accurate and provided in brackets as follows: '[grant number ABX CDXXXXXX]'
- Multiple grant numbers should be separated by a comma as follows: '[grant numbers ABX CDXXXXXX, EFX GHXXXXXX]'
- Agencies should be separated by a semi-colon (plus 'and' before the last funding agency)
- Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number 'to [author initials]'.

An example is given here: 'This work was supported by the National Institutes of Health [P50 CA098252 and CA118790 to R.B.S.R.] and the Alcohol & Education Research Council [HFY GR667789]'.

## Appendix 2 – Search strategy

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials/
4. random allocation/
5. double-blind method/
6. single-blind method/
7. 1 or 2 or 3 or 4 or 5 or 6
8. animal/
9. human/
10. 8 and 9
11. 8 not 10
12. 7 not 11
13. heart failure/ or cardio-renal syndrome/ or dyspnea, paroxysmal/ or edema, cardiac/ or heart failure, diastolic/ or heart failure, systolic/
14. ((heart or cardiac or myocardial) adj1 failure).ti,ab,kw.
15. 13 or 14
16. (self-care or "self care" or self-manag\* or "self manag\*").mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
17. (self adj1 (manag\* or care)).ti,ab,kw.
18. 16 or 17
19. 12 and 15 and 18

### Appendix 3 – Risk of bias table

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Boyne et al	<u>Low</u> "Patients were assigned to a study arm using a computer generated randomisation procedure"	<u>Unclear</u> No information regarding method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>Low</u> "Data analysis was based on the intention to treat principle" (ITT) Missing data balanced across groups and, and reasons similar	<u>Low</u> Protocol not available but all pre-specified and expected outcomes of interest are reported.	<u>Low</u> No additional bias identified.
Clark et al	<u>Unclear</u> No information reported about randomisation process or sequence generation	<u>Unclear</u> No information regarding the method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>High</u> "Bias may have been present for the data about subjective perceptions of the interventions"	<u>Low</u> ITT analysis applied. Similar dropout rate across groups	<u>High</u> Although authors report "two participants lost to follow up were replaced and their data"	<u>High</u> Small sample size, no power calculation
				<i>because the same APRN who conducted the intervention also collected that data"</i>		<i>were eliminated from the analysis", Outcomes reported incompletely, statistics reported but data not included</i>	
Creber et al	<u>Unclear</u> No information reported about randomisation process or sequence generation	<u>Unclear</u> No information regarding the method of concealment	<u>Low</u> "Single blinded" design - participants were not aware of condition allocation.	<u>Low</u> "Two research assistants (blinded to study group allocation) call participants to obtain socio-demographic information and to administer baseline questionnaires"	<u>High</u> Significant drop out (33%) of participants. Numbers not balanced (13% in usual care group and 42% in intervention group). Unclear how missing data has been	<u>High</u> Protocol available in another article (Creber et al., 2015), however, outcomes not reported as pre-specified (self care management scores not reported).	<u>Low</u> No additional bias identified

					accounted for in the analysis		
Dracup et al., 2014	<u>Low</u> "Patients were randomised to 1 of the 3 groups at each site with the use of random selection techniques available in SPSS 18.0"	<u>Low</u> "Randomisation assignment was placed in sealed envelopes"	<u>Low</u> "Participants and their physicians were blinded to group assignment. Research assistants and investigators also remained masked to study arm assignment"	<u>Low</u> "Data were collected at baseline and at 3, 12 and 24 months and were entered directly onto Teleforms and faxed to the Clinical Trials Coordinating Center"	<u>Low</u> "All analyses followed an ITT strategy". Missing data described and balanced across groups.	<u>Low</u> Reference to previous studies with similar protocol and referenced pilot study (Caldwell et al., 2015). The results reflect the hypotheses outlined in the paper	<u>Low</u> No additional bias identified
Hagglund et al., 2015	<u>Unclear</u> No information reported about randomisation process or sequence generation	<u>Unclear</u> No information regarding the method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>Unclear</u> ITT analysis applied but dropout greater in CG than IG.	<u>Unclear</u> No information about study protocol or published reports.	<u>High</u> "There was a statistically higher prevalence of Atrial fibrillation
							in the CG"
Hoban et al., 2013	<u>Low</u> "A coin was tossed to determine if patient would be in monitored or nonmonitored group"	<u>Unclear</u> No information regarding the method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>Unclear</u> No indication of ITT analysis. No reference to missing data, or indication of attrition rates.	<u>High</u> Protocol not available. Outcomes not reported as expected, data missing.	<u>High</u> "The small sample size" of the study. "There were also occasional equipment malfunctions"
Hua et al., 2017	<u>Unclear</u> No information reported about randomisation process or sequence generation	<u>Unclear</u> No information regarding the method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>Unclear</u> No indication of ITT analysis. No reference to missing data, or indication of	<u>High</u> Protocol not available. Outcomes not reported as expected, data missing.	<u>Low</u> No additional bias identified



					attrition rates.		
Mussi et al., 2013	<u>Low</u> "Generated electronically on the website <a href="http://www.randomization.com">www.randomization.com</a> "	<u>Low</u> "One available professional who was not a member of the research group was responsible for the patient allocation list"	<u>Low</u> "Intervention nurses blinded to the patient allocation group until all instruments had been completed in the baseline period. A nurse who was blinded to the group the patient had been allocated to was responsible for the final evaluations"	<u>Low</u> Study registered in Clinical Trials, "blinded for outcome evaluation"	<u>High</u> ITT analysis not applied. Similar dropout rate across groups, reasons for missing data not related to outcome	<u>Low</u> Protocol not available but all pre-specified and expected outcomes of interest are reported.	<u>Low</u> No additional bias identified
Oliveria et al	<u>Low</u> "Randomisation occurred"	<u>Unclear</u> No information regarding the	<u>Unclear</u> No information	<u>Unclear</u> No information regarding	<u>High</u> ITT analysis not applied.	<u>Low</u> Access to protocol	<u>High</u> Small sample
	using simple randomisation , with a random number table"	method of concealment	regarding blinding of participants	blinding of assessors	Similar dropout rate across groups, reasons for missing data not related to outcome	details provided. The results reflect the hypotheses outlined in the paper	size...underpowered due to loss of participants
Rahmani et al	<u>Unclear</u> No information reported about randomisation process or sequence generation	<u>Unclear</u> No information regarding the method of concealment. "To maintain uniform conditions in both groups, random allocation method was used in the intervention and control groups"	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>Unclear</u> No indication of whether ITT was applied. No reference to missing data, or indication of attrition rates.	<u>High</u> Protocol not available. Outcomes not reported as expected, data missing.	<u>High</u> Patients were selected "through the convenient sampling method"
Sezgin et al	<u>Low</u> "Random number table was used as	<u>Unclear</u> No information regarding the method of	<u>Unclear</u> No information regarding	<u>High</u> "Nurse researcher filled out the	<u>Low</u> ITT analysis performed. Details of	<u>Low</u> Protocol not available but all pre-	<u>Low</u> No additional bias

	<i>a simple randomisation method"</i>	concealment	blinding of participants	<i>identifying forms of the patients with HF and the data for the self care of HF index and QoL scale on the basis of the face to face interviews conducted with the patients"</i>	missing data reported	specified and expected outcomes of interest are reported.	identified
Shively et al	<u>Low</u> Stratified block randomisation	<u>Unclear</u> No information regarding the method of concealment	<u>Unclear</u> No information regarding blinding of participants	<u>Unclear</u> No information regarding blinding of assessors	<u>High</u> Proportion of missing data enough to have a clinically relevant effects: "some of the significant effects did show observed	<u>High</u> Details of protocol provided. Outcomes not reported as expected due to missing data	<u>High</u> Small sample size, gender bias

					<i>power less than 0.80"</i>		
Souza et al	<u>Low</u> "Generated electronically on the website <a href="http://www.randomization.com">www.randomization.com</a> "	<u>Low</u> "Professional who was not a member of the research group was responsible for the patient allocation list	<u>Low</u> "Intervention nurses blinded to the patient allocation group until all instruments had been completed in the baseline period. A nurse who was blinded to the group the patient had been allocated to was responsible for the final evaluations"	<u>Low</u> Study registered in Clinical Trials, "blinded for outcome evaluation"	<u>Low</u> ITT analysis was used. Similar dropout rate across groups.	<u>Low</u> Protocol not available but all pre-specified and expected outcomes of interest are reported.	<u>Low</u> No additional bias identified
Yu et al	<u>Low</u> "Computer-	<u>Unclear</u> No information	<u>Unclear</u> No	<u>Low</u> "Another	<u>Unclear</u> ITT analysis	<u>Low</u> Protocol	<u>High</u> Gender

	<i>generated random number sequence was used"</i>	regarding the method of concealment	information regarding blinding of participants	<i>nurse who had no information about subjects status...collected post test data"</i>	implemented. Reasons for missing data "not related to or due to the values of the outcomes themselves" 'Higher dropout rate in the control group than in the intervention group resulted in mortality bias"	details provided. The results reflect the hypotheses outlined in the paper	bias
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## **Appendix 4 – Submission requirements for Psychosis: Psychological, Social and Integrative Approaches**

Journal

**Psychosis**

Psychological, Social and Integrative Approaches

### **Preparing Your Paper**

All authors submitting to medicine, biomedicine, health sciences, allied and public health journals should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, prepared by the International Committee of Medical Journal Editors (ICMJE).

### ***Structure***

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

### ***Word Limits***

Please include a word count for your paper.

The maximum word length for an Article in this journal is 6000 words (this limit includes tables, references and figure captions).

The maximum word length for a First Person Account is 3500 words.

The maximum word length for a Brief Report is 1500 words.

The maximum word length for an Opinion Piece is 1500 words.

The maximum word length for Letters to Editor is 400 words.

The maximum word length for a Book Review is 1000 words.

### ***Style Guidelines***

Please refer to these quick style guidelines when preparing your paper, rather than any published articles or a sample copy.

Any spelling style is acceptable so long as it is consistent within the manuscript.

Please use double quotation marks, except where “a quotation is ‘within’ a quotation”. Please note that long quotations should be indented without quotation marks.

### ***Formatting and Templates***

Papers may be submitted in Word format. Figures should be saved separately from the text. To assist you in preparing your paper, we provide formatting template(s).

Word templates are available for this journal. Please save the template to your hard drive, ready for use.

If you are not able to use the template via the links (or if you have any other template queries) please contact us here.

### **References**

Please use this reference guide when preparing your paper.

An EndNote output style is also available to assist you.

### **Checklist: What to Include**

1. **Author details.** Please ensure everyone meeting the International Committee of Medical Journal Editors (ICMJE) requirements for authorship is included as an author of your paper. All authors of a manuscript should include their full name and affiliation on the cover page of the manuscript. Where available, please also include ORCiDs and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted. Read more on authorship.
2. Should contain a structured abstract of 200 words.
3. You can opt to include a **video abstract** with your article. Find out how these can help your work reach a wider audience, and what to think about when filming.
4. Between 5 and 6 **keywords**. Read making your article more discoverable, including information on choosing a title and search engine optimization.
5. **Funding details.** Please supply all details required by your funding and grant-awarding bodies as follows:  
*For single agency grants*  
This work was supported by the [Funding Agency] under Grant [number xxxx].  
*For multiple agency grants*  
This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx]; and [Funding Agency #3] under Grant [number xxxx].
6. **Disclosure statement.** This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research. Further guidance on what is a conflict of interest and how to disclose it.
7. **Data availability statement.** If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). Templates are also available to support authors.
8. **Data deposition.** If you choose to share or make the data underlying the study open, please deposit your data in a recognized data repository prior to or at the time of

- submission. You will be asked to provide the DOI, pre-reserved DOI, or other persistent identifier for the data set.
9. **Supplemental online material.** Supplemental material can be a video, dataset, files, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare. Find out more about supplemental material and how to submit it with your article.
  10. **Figures.** Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour, at the correct size). Figures should be supplied in one of our preferred file formats: EPS, PS, JPEG, GIF, or Microsoft Word (DOC or DOCX). For information relating to other file types, please consult our Submission of electronic artwork document.
  11. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
  12. **Equations.** If you are submitting your manuscript as a Word document, please ensure that equations are editable. More information about mathematical symbols and equations.
  13. **Units.** Please use SI units (non-italicized).

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#### Disclosure Statement

Please include a disclosure statement, using the subheading "Disclosure of interest." If you have no interests to declare, please state this (suggested wording: *The authors report no conflict of interest*). For all NIH/Wellcome-funded papers, the grant number(s) must be included in the declaration of interest statement. Read more on declaring conflicts of interest.

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### ***Consent***

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Authors are further encouraged to cite any data sets referenced in the article and provide a Data Availability Statement.

At the point of submission, you will be asked if there is a data set associated with the paper. If you reply yes, you will be asked to provide the DOI, pre-registered DOI, hyperlink, or other persistent identifier associated with the data set(s). If you have selected to provide a pre-registered DOI, please be prepared to share the reviewer URL associated with your data deposit, upon request by reviewers.

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## Appendix 5: Interview Schedule

### INTERVIEW SCHEDULE

**Study: Experience of living with a mental health problem and heart failure.**

#### Introduction

Interviewer will welcome participant, introduce self and thank participant for coming along.

Interviewer will then explain research: *"I am researching people's experience of living with a mental illness and a heart problem. I'll be asking you some questions about what it is like to live with both illnesses, the challenges of living with both illnesses, what you think about your treatment, and how you cope with living with both illnesses. I'm really interested in learning about your experience"*.

Participant will then be shown recording equipment, and process of confidentiality and safe record keeping is explained.

*"What we talk about today is confidential and will not be shared with your nurse or anyone else involved in your care. However, if you tell me that you or someone else is at risk of harm, then I have a duty of care to report this to a relevant member of staff in order to keep you or someone else safe. Do you understand?"*

Interviewer will then go through information sheet and consent form; ask participant to sign consent form.

*"I know that some things we talk about today might be upsetting to talk about. You can take a break at any point during the interview, just let me know. Also, you don't have to answer any questions you don't want to"*.

Interviewer will ask participant if they have any questions before beginning interview.



### **Illness identity**

Can you tell me your experience of how you found out that you had a problem with your heart?

P: what was it like for you? How did it make you feel? Impact on mental health?

What is your understanding of your heart problem now?

P: how have you made sense of your difficulty?

Can you tell me your experience of living with a mental health problem?

P: when did you find out? What is it like for you?

What's it like explaining your illnesses to others?

P: the experience of telling other people about illnesses

### **Treatment**

Can you tell me about what your treatment plan involves?

P: What do you need to do? Changes that you have had to make? Do you think treatment is appropriate? How does it feel having to stick to treatment plan? Do you think it works?

Some people describe difficulties sticking to their treatment plan – is this something you can relate to?

P: too many meds, attending apps etc.

What, if anything, helps you follow your treatment plan?

P: some people find it helpful if they have help from others, such as family/friends/care staff)

### **Living with illness**

Has having a mental health problem and a heart problem affected your life? How?

P: what has changed for you? Any negative changes, such as inability to do things used to do, burden on others. Any positive changes, such as warning sign, taking things slower?

Have there been any challenges with living with both a mental health problem and a heart problem? What?

Interview Schedule (22<sup>nd</sup> September 2017, Version 5).



Is there anything that helps you?

P: friends, talk to people/support from others, continue to do thing you enjoy?)

**Closing question**

Before we finish, is there anything about your experience that we have not covered that you would like to share?

**General prompts:**

How was that for you?

Can you tell me a bit more about that

I'm interested to hear more about...

How did you feel when...

Earlier you mentioned...tell me a bit more about that

What was that like for you?

What do you think about that?

How did you make sense of that?

**Interview Schedule (22<sup>nd</sup> September 2017, Version 5).**

## Appendix 6: Ethical Approval



East of Scotland Research Ethics Service (*EoSRES*)

Research Ethics Service

Tayside medical Science Centre  
Residency Block Level 3  
George Pirie Way  
Ninewells Hospital and Medical School  
Dundee DD1 9SY

Dr Michelle Rankin  
c/o Institute of Health & Wellbeing  
University of Glasgow, 1st floor  
Administration Building,  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Date: 11 January 2018  
Your Ref:  
Our Ref: LR/AG17/ES/0125  
Enquiries to: Arlene Grubb  
Direct Line: 01382 383848  
Email: [eosres.tayside@nhs.net](mailto:eosres.tayside@nhs.net)

Dear Dr Rankin

**Study title:** The experience of living with a severe mental illness and heart failure - An interpretative phenomenological study.  
**REC reference:** 17/ES/0125  
**Protocol number:** Protocol version 4  
**Amendment number:** AM01 (REC Reference only)  
**Amendment date:** 30 November 2017  
**IRAS project ID:** 228070

The above amendment was reviewed at the meeting of the Sub-Committee held on 11 January 2018 in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	AM01	30 November 2017
Sponsor Approval		15 December 2017
Caldicott Guardian Approval Email		05 December 2017
RAS REC Form		21 December 2017
Caldicott approval letter		05 December 2017
Participant information sheet (PIS)	7	24 November 2017
Participant information sheet (PIS) [Staff]	8	13 December 2017
Research protocol or project proposal	9	13 December 2017



Summary CV for Chief Investigator (CI) [Professor Andrew Gumley]		
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### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

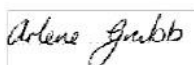
### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>17/ES/0125:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely



**PP Dr Anthony Davis**  
**Vice Chair**

E-mail: eosres.tayside@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Miss Sophie Bagnall, NHS Greater Glasgow and Clyde



**East of Scotland Research Ethics Service REC 2**

**Attendance at Sub-Committee of the REC meeting on 11 January 2018**

**Committee Members:**

<b>Name</b>	<b>Profession</b>	<b>Present</b>	<b>Notes</b>
Dr Anthony Davis	Consultant Anaesthetist	Yes	Chair
Mr Jeremy Wickins	Lecturer in Law	Yes	

**Also in attendance:**

<b>Name</b>	<b>Position (or reason for attending)</b>
Mrs Arlene Grubb	REC Assistant



## Appendix 7: R&D Approval



Administrator: Sophie Bagnall  
Telephone Number: 0141 232 1826  
E-Mail: [sophie.bagnall@ggc.scot.nhs.uk](mailto:sophie.bagnall@ggc.scot.nhs.uk)  
Website: [www.nhsggc.org.uk/r&d](http://www.nhsggc.org.uk/r&d)

R&D Management Office  
West Glasgow ACH  
Dalnair Street  
Glasgow G3 8SW

5 October 2017

Dr Michelle Rankin  
Trainee Clinical Psychologist  
NHS Greater Glasgow & Clyde  
Institute of Health and Wellbeing  
Gartnavel Royal Hospital  
1055 Great Western Road  
G12 0XH

### NHS GG&C Board Approval

Dear Dr Rankin

<b>Study Title:</b>	<b>The experience of living with a severe mental illness and heart failure - An interpretative phenomenological study</b>
<b>Principal Investigator:</b>	<b>Dr Michelle Rankin</b>
<b>GG&amp;C HB site</b>	<b>NHS GG&amp;C Cardiology Departments and General Practice</b>
<b>Sponsor</b>	<b>NHS Greater Glasgow &amp; Clyde</b>
<b>R&amp;D reference:</b>	<b>GN17MH446</b>
<b>REC reference:</b>	<b>17/ES/0125</b>
<b>Protocol no:</b>	<b>V7 04/10/17</b>

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

#### Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
  - a. During the life span of the study GGHB requires the following information relating to this site
    - i. Notification of any potential serious breaches.
    - ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy ([www.nhsggc.org.uk/content/default.asp?page=s1411](http://www.nhsggc.org.uk/content/default.asp?page=s1411)), evidence of such training to be filed in the site file

2. **For all studies** the following information is required during their lifespan.
- a. Recruitment Numbers on a monthly basis
  - b. Any change of staff named on the original SSI form
  - c. Any amendments – Substantial or Non Substantial
  - d. Notification of Trial/study end including final recruitment figures
  - e. Final Report & Copies of Publications/Abstracts

**Please add this approval to your study file as this letter may be subject to audit and monitoring.**

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,



Sophie Bagnall  
Senior Research Administrator

**cc. Ms Emma-Jane Gault, University of Glasgow**

## Appendix 8: Caldicott Guardian Approval

### Application for Caldicott Guardian Approval



**NOTE:** You must address the 6 Caldicott principles (Appendix A) when submitting this application.

#### 1. Study / Project Title

Living with a mental health problem and heart failure.

#### 2. Please tick the type of study/project you are undertaking

Audit ☐ Research ☒ Service Improvement ☐ Other ☐

If other, please provide further details:

#### 3. Who is providing clinical support for the study / project (this should be someone from NHSGGC such as a Clinical Director and be different from the person requesting the information)

Name: Dr John Sharp

Designation: Consultant Clinical Psychologist, Scottish National Advanced Heart Failure Service, Golden Jubilee National Hospital, Clydebank, G81 4DY

Email Address or Telephone Number: johnsharp@nhs.net

#### 4. Details of individual / organisation requesting data

Name: Michelle Rankin

Designation: Trainee clinical psychologist, University of Glasgow, NHS GGC

Work/University Address:

Institute of Mental Health & Wellbeing,  
University of Glasgow  
Administration Building,  
1<sup>st</sup> Floor  
Garthavel Royal Hospital  
1055 Great Western Road  
Glasgow G12 0XH

Contact Number: 0141 211 0607

#### 5. Purpose for which data are to be used (Principle 1)

To identify patients who have both a severe mental health illness and heart failure. The data will attempt to match CHI numbers from a database that includes all patients open to HF nurses across NHS GGC and a database that includes patients who are on anti-psychotic medication (Psychological Clinical Information System (PsyCIS), NHS GGC.

Identified patients will be passed onto heart failure team and the patients' nurses will be asked to comment on the patient's eligibility to participate in the above research study. Patients who are deemed eligible will be given an information sheet at their next clinical appointment. The information sheet will provide details of the study. Patients can then decide if they would like to participate in the study. If they agree, the researcher will contact patient and provide more details about the study. Patient can decide at any stage that they no longer wish to participate, with no consequences. Data that has been already collected for the patient will be destroyed.

**6. Which identifiable data items are required? Please detail why these are required.**  
(Principles 2 and 3)

PID Required	✓	Justification
CHI Number	✓	CHI numbers from both databases will be transferred to an excel spreadsheet to identify matches between the databases. The database will be stored on an NHS computer and will be password protected, only accessible to the researcher.
Forename		
Surname		
DOB		
Age		
Gender		



Address		
Post code (full)		
Post code (partial)		
Clinical data		
Other (please specify)		

**7. Who will have access to this information? (Principle 4)**

Internal: Researcher only.

External: n/a

**8. Storage and use of personal data during the audit/project (Principle 5)**

Will you be undertaking any of the following activities at any stage (including the identification of potential participants)? Please tick as appropriate.

- ☐ Access to Health Record (paper)
- ☐ Access to Health Record (electronic)
- ☐ Sharing of identifiable data with other organisations (provide further detail below)
- ☐ Publication of data (if this could identify individuals provide further detail below)
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal identifiable data on any of the following:
  - ☐ Manual files, including x-rays
  - ☒ NHS Computers
  - ☐ Home or other personal computers
  - ☐ University computer
  - ☐ Private company computer
  - ☐ Laptop computer (or any other mobile device)
  - ☐ USB Flash Drive

Additional Information:

**9. Destruction of Data**

How long will the data be held?

The data will be held until the end of the project, approximately June 2018.

How will the data be destroyed?

The data will only be stored on an NHS computer, the file will be deleted and removed off the computer permanently, once the project is complete.

**10. Please provide your organisation's Data Protection Registration Number (if external to NHSGGC)**

**Note:**

- Copies of any other relevant supporting documentation (e.g. ethics approval, patient information leaflet etc.) should be attached to this application
- Appendix A details the Caldicott Principles

**Person responsible for the requested data**

**Name** .....Michelle Rankin.....

**Designation** Trainee Clinical Psychologist, University of Glasgow, NHS GGC

**Signature:** .....M Rankin..... **Date:**...04/12/2017.....

The release of data as described above is: approved / not approved

**Caldicott Guardian** .....*LBrown*..... **Date** .....05/12/17.....

## Appendix 9: Staff Information Leaflet



Institute of Health  
& Wellbeing



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### STAFF INFORMATION LEAFLET

#### Living with a Mental Health Problem and Heart Failure

I would like to ask you to take a few minutes to read over this information leaflet. My name is Dr Michelle Rankin and I am a Trainee Clinical Psychologist with the University of Glasgow. As part of my Doctorate in Clinical Psychology I am undertaking a research project investigating the experience of patients who live with both a severe mental illness and heart failure.

#### What is the purpose of the study?

The purpose of the study is to try to better understand the experience of people living with a severe mental illness and heart failure. It is hoped that the study will provide us with a better understanding of the experiences and challenges that people living with both illnesses face. It is also hoped that it will help understand how we can better support people with both conditions, and shape future research and interventions.

#### What does the study involve?

The study involves interviewing participants who have a diagnosis of a severe mental illness, such as psychosis or schizophrenia, and heart failure. Participants must meet the following criteria:

- Aged 18 years or over
- Been diagnosed with heart failure for at least 1 year
- Taking prescribed mood stabiliser (lithium) or anti-psychotic medication
- In a stable condition (judged by clinical team and researcher)
- Recorded and/or patient reported diagnosis of psychosis/schizophrenia/bipolar disorder
- Speak English
- No medical comorbidity or cognitive impairment

Patients who meet the above criteria and who have agreed to participate will take part in a semi-structured interview, which will last approximately one hour. The interview will be carried out in a NHS setting that is convenient to the patient, such as their GP surgery. Patients will be asked to sign a consent form before they participate and they can opt-out of participation at any time. No patient identifiable information will be stored.

Staff information leaflet 13<sup>th</sup> December 2017, Version 8.

**How can I help?**

It is hoped that either you or I can identify patients from your caseload who have both a severe mental health difficulty and heart failure. This can be done through discussion with you about your caseload, or I may be able to identify patients by matching up CHI numbers from your caseload with CHI numbers from a database that stores a list of patients in NHS GGC who are taking antipsychotic medication.

I would be grateful if you could spare some time with me to discuss the identified patient/s, to determine whether you feel they meet the eligibility criteria, based on your clinical judgement.

If your patient/s do meet the criteria and are deemed eligible for participation, I would ask that you make your patient aware of the study during your next contact. At this stage, you will provide verbal information and an information sheet about the study to potential participants. If your patient agrees to participate at this stage, and they give verbal consent for you to pass their contact details onto me, I will contact the participant by telephone to answer further study related questions and offer an appointment for an interview. I can also be available at clinic to answer any questions that your patient may have about the study.

**What happens next?**

I will contact your patient, explain the details of the study and answer any questions that they may have. At this stage, your patient will be reminded that participation is optional, and even if they do decide to participate, they can withdraw their participation at any stage. If they agree to participate at this stage, an appointment will be made to conduct the interview.

**Do people have to take part?**

No. Individuals do not have to take part and even if they do decide to take part, they can withdraw from the study at any point if they change their mind.

**What happens to the information?**

The audio recordings and any written information will be kept under password on a locked NHS computer and transferred to a secure Glasgow University network once the study has been completed. The data will be kept here for ten years, after which time the information will be destroyed. This information will be stored in accordance with the Data Protection Act, which means that we lock it securely and cannot reveal it to others without prior permission.

Your patient/s' name and any personal information will be known to the researchers but will be saved separately from your audio recording. Sometimes, representatives of the study sponsor, NHS Greater Glasgow and Clyde, may look at their personal information and records. This is to make sure that the researcher is conducting the study correctly.

The results of this study may be published in academic journals, conference proceedings and as a piece of work for a doctoral qualification in Clinical

Psychology. Some direct quotes from your patient/s' interview may be included in these reports/publications, however all information will be anonymised and it will not be possible to personally identify them from this information.

**What are the possible benefits of taking part?**

Participation will help develop an understanding of the challenges of living with both a mental illness and heart failure. It is hoped that your patient/s may find some benefit from having the chance to talk about their experiences.

At any point, if they feel distressed during or after the interview, we will ensure that they have information on how to access appropriate supports, if they need to.

**Are there any down sides to participants taking part?**

It is possible that the discussions may trigger upsetting thoughts or feelings that may be difficult for the participant to talk about. If this is the case, and the participant wishes to stop, they can end the interview at any time. If they do become upset, they will be signposted to relevant supportive services.

**Who has reviewed the study?**

To make sure the study is being conducted correctly, it has been reviewed by the East of Scotland Research Ethics Committee and the NHS Greater Glasgow and Clyde Research & Development Department.

**What if something goes wrong?**

If you have any concerns about the study or the way it is conducted or if you want to complain about any aspect of this study, please contact Dr John Sharp, Scottish National Advanced Heart Failure Service, Golden Jubilee National Hospital, Clydebank, G81 4DY. Email: [johnsharp@nhs.net](mailto:johnsharp@nhs.net) . Tel: 0141 951 5484

**If you have any further questions...**

Please do not hesitate to contact me should you have any questions about the study, or you would like further information. Below is contact information for all researchers involved in the study:

Researcher(s) Contact Details:
<p><u>Dr Michelle Rankin, Trainee Clinical Psychologist</u> Institute of Mental Health &amp; Wellbeing, University of Glasgow Administration Building, 1<sup>st</sup> Floor Gartnavel Royal Hospital 1055 Great Western Road Glasgow G12 0XH Email: <a href="mailto:m.rankin.1@research.gla.ac.uk">m.rankin.1@research.gla.ac.uk</a> Tel: 0141 211 0607</p>



Dr John Sharp  
Consultant Clinical Psychologist  
Scottish National Advanced Heart Failure Service  
Golden Jubilee National Hospital,  
Clydebank, G81 4DY  
Email: [johnsharp@nhs.net](mailto:johnsharp@nhs.net)  
Tel: 0141 951 5484

Professor Andrew Gumley  
Institute of Health & Wellbeing, University of Glasgow  
Administration Building, 1<sup>st</sup> Floor  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow G12 0XH  
Email: [andrew.gumley@glasgow.ac.uk](mailto:andrew.gumley@glasgow.ac.uk)  
Tel: 0141 211 0607

## Appendix 10: Participant Information Sheet



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### PARTICIPANT INFORMATION SHEET

#### **Living with a mental health problem and heart failure.**

We would like to invite you to take part in a research study. To help you decide if you would like to take part, you need to understand what taking part would involve for you. Please take your time and read the following information carefully.

#### **Who is conducting the research?**

The research is being carried out by Dr Michelle Rankin, who is a Trainee Clinical Psychologist from the University of Glasgow. The research is being supervised by Professor Andrew Gumley, Professor of Psychological Therapy from the University of Glasgow, and Dr John Sharp, Consultant Clinical Psychologist from the Scottish National Advanced Heart Failure Service.

#### **What is the purpose of the study?**

The purpose of the study is to help better understand the experience of living with a mental illness and heart failure. The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Glasgow.

The study will involve talking to people who have a diagnosis of a mental illness (recorded and/or patient reported diagnosis of bipolar disorder, schizophrenia or psychosis) and heart failure. We know that psychotropic medication and lifestyle choices can impact cardiac function and mental health. Thus, all participants will be asked about their experience of managing both illnesses (such as medication adherence, healthy eating), their experience of living with both illnesses and their understanding of their illnesses. It is hoped that the interviews will provide us with a better understanding of the experiences and challenges that people living with both

illnesses face. It is also hoped that this will help us understand how we can better support people with both conditions shape future research and interventions.

#### **Why have I been invited?**

We are inviting people who are currently receiving treatment for both a mental illness (such as bipolar disorder, schizophrenia or psychosis) and heart failure. We believe that you may fit these criteria and that is why we have invited you to take part.

#### **What does taking part involve?**

If you decide to take part in the study, you will be asked to:

1. Let your nurse or cardiologist know that you are happy to learn more about the study and they will pass your details to Michelle Rankin who will telephone you. Michelle can also be available at clinic to answer any questions you may have about the study.
2. Michelle will give you more information about the study, answer any questions you have, and ask you some questions about your health. If you still would like to take part, she will arrange an appointment time with you. The appointments will take place in a hospital clinic, or it may be possible to conduct the interview at your GP surgery.
3. Before you begin the interview, Michelle will ask you to sign a consent form to say you agree to take part in the study.
4. Your interview will last around one hour and will be an informal discussion. Michelle will ask you some questions about your illnesses and how you manage your treatment.

You are welcome to bring someone you know with you to the interview. You can take a break at any time during the interview and you don't have to answer any questions that you don't want to.

The interviews will be audio recorded to make sure that what is written down in the study matches exactly what each participant says. Some quotes from your interview may be included in the research paper, but all information will be anonymised.

#### **Do I have to take part?**



No. Your decision to take part or not to take part is entirely up to you. If you agree to take part, you will be asked to sign a consent form before you start your interview, so that there is a record of your consent.

You are allowed to leave the study at any point without giving a reason. If you choose to leave the study, your data will be removed from the study, up to the point when the research is written up. The decision to leave will not affect the care or support you receive now, or in the future.

#### **What happens to the information?**

We will write to your GP and nurse/cardiologist so that they are aware that you are taking part in the study. If issues arise during the interview I will discuss this with you, and make you aware of the possibility of sharing this information with your nurse/cardiologist.

The audio recordings and any written information will be kept under password on a locked computer and transferred to a secure University of Glasgow network once the study has been completed. The data will be kept here for ten years, after which time the information will be destroyed. This information will be stored in accordance with the Data Protection Act, which means that we lock it securely and cannot reveal it to others without prior permission. The data that we collect from you will only be used for this study. It will not be re-used by any other investigators.

Your name and any personal information will be known to the researchers but will be saved separately from your audio recording. Sometimes, representatives of the study sponsor, NHS Greater Glasgow and Clyde, may look at your personal information and records. This is to make sure that the researcher is conducting the study correctly.

The results of this study may be published in academic journals, conference proceedings and as a piece of work for a doctoral qualification in Clinical Psychology. Some direct quotes from your interview may be included in these reports/publications, however all information will be anonymised and it will not be possible to personally identify you from this information.

We are keen to obtain feedback on the emerging themes from the study. If you are interested, we can send you some of the initial findings from the study and ask you for provide feedback on the extent to which you feel they represent your experience.

In addition, if you feel you would like to receive a copy of the findings from the study please let Michelle know, who will be happy to send you a copy.

#### **What are the possible benefits of taking part?**

Your participation will help develop an understanding of the challenges of living with both a mental illness and heart failure. It is hoped that you may find some benefit from having the chance to talk about your experiences.

At any point, if you feel distressed during or after the interview, we will ensure that you have information on how to access appropriate supports, if you need to.

#### **Who has reviewed the study?**

The East of Scotland Research Ethics Service REC 2, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Greater Glasgow & Clyde, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

#### **What if you have a complaint about any aspect of the study?**

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint procedure is also available to you. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through NHS Greater Glasgow & Clyde, who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager:

Complaints Department,  
West Glasgow Ambulatory Care Hospital,  
Dalnair Street  
Glasgow  
G3 8SJ  
Phone: 0141 201 4500  
Email: [complaints@ggc.scot.nhs.uk](mailto:complaints@ggc.scot.nhs.uk)

## Appendix 11: GP letter



**Institute of Mental Health & Wellbeing**  
University of Glasgow  
Administration Building, 1<sup>st</sup> Floor  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow G12 0XH  
Contact: Dr Michelle Rankin/ Professor Andrew Gumley  
Email: [m.rankin.1@research.gla.ac.uk](mailto:m.rankin.1@research.gla.ac.uk) [andrew.gumley@gla.ac.uk](mailto:andrew.gumley@gla.ac.uk)

Date:

Dear Dr \_\_\_\_\_

**Research project: Living with a mental health problem and heart failure.**

We are writing to inform you that \_\_\_\_\_ (D.O.B. \_\_\_\_\_), recently provided us with their consent to participate the above named research study. They have given us permission to write to you, as their GP, to inform you of their participation in the research.

The research is a qualitative study exploring the experiences of people diagnosed with a severe mental illness, such as psychosis or schizophrenia, and heart failure. It will involve asking people about their experience of what it is like to live with their illnesses, how they manage their treatment of their illnesses and how having these illnesses has affected their life. Enclosed is a copy of the participant information sheet which provides further details about the nature and purpose of the study.

If you require any additional information then please do not hesitate to contact us, using the contact details provided above.

Yours sincerely

Michelle Rankin  
Trainee Clinical Psychologist

Supervised by Professor Andrew Gumley  
Professor of Psychological Therapy

Encl. Participant Information Sheet

CC: Patient's nurse/cardiologist

## Appendix 12: Consent Form



Institute of Health  
& Wellbeing



### Consent Form

**Title of project:** Living with a mental health problem and heart failure

**Name of researcher:** Dr Michelle Rankin

**Patient identification number for this study:**

Please initial the box

1. I confirm I have read and understood the information sheet Version No: (date) for the above study. ☐
2. I understand that my participation is voluntary and confidential and that I am free to leave the study at any time without giving any reason, without my current or future treatment being affected. ☐
3. I understand that if I withdraw consent from the study, the information collected up to that point will be destroyed. ☐
4. I give permission for the interview to be audio recorded. ☐
5. I agree that you may inform my general practitioner, and my nurse or cardiologist, of my involvement in the study. ☐
6. I understand that if issues arise during the interview, the researcher will inform me of this and discuss the possibility of sharing this with my health care team. ☐
7. I understand that my medical notes and data collected during the study may be looked at by individuals from the research team, regulatory authorities or from the study Sponsor where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information. ☐
8. I agree that fully anonymised quotations may be used in publications and other materials arising from the study. ☐
9. I would like to receive a copy of the study results. ☐

Consent form Version 4 14<sup>th</sup> September 2017

Subject Name	Date	Signature
.....	... / ... / .....	.....
Researcher	Date	Signature
.....	... / ... / .....	.....

***Thank you for agreeing to take part in this research***



## Appendix 13: Extract from Interview (Jane)

LINGUISTIC  
DESCRIPTIVE  
CONCEPTUAL

Experience of  
being ill

Really bad

Participant 1 Jane. Duration: 60.03

Living with a Severe Mental Illness and Heart Failure. Researcher: Michelle Rankin

1 Today is about trying to get an understanding from you about what it's  
2 like living with heart failure and a mental health problem. So I was  
3 wondering if, first of you, would you mind telling me about your  
4 experience of how you found out that you had a problem with your  
5 heart?

6  
7 Well yeah, eh, well he it was my asthma, I've had asthma all my life (pause)  
8 and it just got out of control (pause). I had a job at the time emm, it was a  
9 cleaning job (pause) emm I had to take that job on because I got all my  
10 benefits taken away from me so I said oh god what am I gonna do I'm  
11 gonna have to go out and work eh, so I did, emm, so I did

12  
13 What was that like for you?

14  
15 Really bad, really bad, I struggled terribly, terribly. It was a cleaning job, and  
16 my asthma started getting out of control, really, really breathless and I  
17 struggled a few times just to get into work, eh, 3 times over the space of  
18 over 6 months, I was hospitalised, my asthma so bad, having really bad  
19 asthma attacks, so so bad, I as also taking panic attacks aswell, when I was  
20 having asthma attacks (gosh), first time it took emm, the doctors my third  
21 admission before I was em, before the heart failure was detected, so the  
22 first time (pause) it was terrible.

23  
24 When was this if you don't mind me asking?

25  
26 This was emm, God, about (pause) God it doesn't even seem that long ago  
27 but it was about 10 years ago, (pause) where's all these year gone (slight  
28 laugh) but emm the first time I got admitted into hospital, really bad asthma  
29 attack, panic attacks, emm, (pause) I was in a bad way, I was getting the  
30 doctors were, pumping adrenaline into me (uh huh) I was really in a bad

Had asthma all her life

- Worry? Not having a choice,  
loss of control?

She had to go back to work

Repeat "really bad" +  
"struggled terribly"

- how must this have  
felt,

trying to emphasise just  
how difficult this  
experience was for her

Happened 10 years ago

1 "I was in a bad way"  
repeat of word bad.

Participant 1 Jane. Duration: 60.03  
 Living with a Severe Mental Illness and Heart Failure. Researcher: Michelle Rankin

Scary

Uncertainty

Scary

Overwhelming  
 thoughts & emotions

31 way, it was scary, my, my daughters were there aswell, it must've been  
 32 awful for them, but we managed to emm (pause) get it under control but  
 33 again the second time happened and I still continued to work (ok) emm I  
 34 think I only lasted about, god (pause) I'm not sure, but I ended up I lost my  
 35 job, because, enough was enough, my health had deteriorated, but the  
 36 second time again, really bad asthma attack, panic attack, emm, took to  
 37 hospital and I remember the doctor coming in from intensive care (pause)  
 38 and then they thought they were gonna have to take me into intensive care,  
 39 and they were just kind of telling me a wee bit about it and not to be  
 40 alarmed, and we might need to do this, but it didn't happen thankfully, thank  
 41 god it didn't happen, emm (pause)

42  
 43 **How was that experience?**

44  
 45 I was just horrible. I just couldn't breath, just couldn't breath, it was horrible,  
 46 really horrible, scary, very very scary, thinking my times up, this is it, umm,  
 47 its gonna kill me, I'm gonna die, its like I seeing my life flash in front of me I  
 48 thought this is it, eh we managed to overcome and we managed to get my  
 49 breathing again under control, I didn't need to go into intensive care or that,  
 50 but I remember getting took up to the ward and the nurse, funny one of the  
 51 nurses came and went, oof thought we were gonna have to put you onto a  
 52 blower there, I take it she meant, I just heard her say this, eh what did she  
 53 mean by that and then I thought she must mean a life support machine.

54  
 55 **How did you feel about that?**

56  
 57 Scared, very scared. And just exhausted, very very exhausted, just totally,  
 58 you're fighting you're actually fighting for your life, that's what it felt like,  
 59 that's exactly what it felt like, emm, again, no diagnosis as to what was  
 60 happening. I've had asthma all my life, and that was the worst (pause) the

"enough was enough"

Experience of being so ill -  
 being told about intensive care

Relief - how scary that  
 experience must have been  
 for her.

"my times up" "I'm gonna die"  
 "seeing my life flash in front of  
 me".

Powerful language to express  
 how difficult, horrible & scary  
 the experience was. -  
 overwhelming thoughts/emotions

Repeat word "scared"  
 "fighting for your life"

did she think she may be losing  
 the fight?

This experience was the worst  
 she had been through



Participant 1 Jane. Duration: 60:03

Living with a Severe Mental Illness and Heart Failure. Researcher: Michelle Rankin

Struggling to cope

Scary

Relief

Diagnosis - how it felt.

Coming to terms with/making sense of diagnosis - what it means

61 worst time I've ever had with my asthma so again it happened a third time  
62 and I thought oh my god please I can't get on like this and at that time I was  
63 annoyed and I thought, I need to know what's going on I've had enough I  
64 need to know what's going on I'm gonna end up its gonna kill me there's  
65 nothing worse when you're fighting to breath and you think your hearts just  
66 (pause) you think your hearts just gonna stop as well coz it must be a  
67 terrible strain on my heart and I'm fighting for my, to breath like that, so it  
68 was very very scary emm, but then I got my diagnosis the third time, and  
69 what a relief, such a relief to get diagnosis and get put on medication, and I  
70 got put on, ehh the first tablet I got put on I think I was, ehh I don't know eh,  
71 but I just remember the first time getting medication for my, for heart failure,  
72 it was like a wonder pill, I was like oh my god it was just so, my breathing, It  
73 was an instant relief, just an instant relief and then I was able to do things  
74 that I couldn't do, like even just walking or a wee bit of lifting, it was just like,  
75 like a new lease of life that this heart medication, total new lease of life,  
76 emm but that yeah, that was, eh, I've had the diagnosis of heart failure now  
77 for about 10 year now  
78

79 **Ok Ok, thank you for telling me all that. You said there about getting**  
80 **that diagnosis, were you in the hospital at the time, and who was it**  
81 **that actually told you that you had the diagnosis?**  
82

83 Dr XX, I remember Dr XX and he's a lovely doctor and he's such a brilliant  
84 doctor, yeah it was him, when I saw it was a relief, (pause) and the  
85 medication was absolutely amazing as well, but it after getting discharged  
86 from hospital and then I think my mental emm condition or eh mentally I  
87 started being affected, I thought oh god I've got a heart condition, that's,  
88 that's scary, I've got a heart that's impaired, that's not working properly and  
89 I could die and, took me really, to get my head around.  
90

really get the sense of her  
struggle at this time

"fighting" "very, very scary" Getting diagnosis of HF

"relief, such a relief" - repeated  
now it must have felt to go  
through such a difficult  
experience + then finally get on  
answer + get the correct  
support.

"like a wonder pill"

"Oh God I've got a heart  
condition"

trying to make sense of  
the diagnosis



Participant 1 Jane. Duration: 60.03  
Living with a Severe Mental Illness and Heart Failure. Researcher: Michelle Rankin

91 **How did that make you feel?**

92  
93 Down (pause) eh, (pause) down, I wouldn't say depressed, emm no, but  
94 emm rather down and fed up and just worrying, just really worried and emm  
95 (long pause) but as the years gone on I found I couldn't do what I used to  
96 be able to do, having the heart condition

97  
98 **Can you tell me a bit more?**

99  
100 Its (pause) its life restricting (pause). I used to love walking (pause) can't do  
101 that anymore but eh I get a new drug today (ok) so emm I've been  
102 prescribed new drug today which I'm keen to try so ehh I'm hoping eh I'm  
103 hoping, I've heard it's a really good drug, its actually two drugs so I'm really  
104 keen to start on that and hopefully, yeah emm yeah

105  
106 **I hope it goes well for you. So tell me, what's your understanding of**  
107 **your heart problem just now then?**

108  
109 (pause) as I said its life restricting emm I still get scared sometimes (pause)  
110 emm (pause) I try not to let it get me down, but eh, but it does, it scares me,  
111 and I'm scared in case I die young from it, that scares me sometimes  
112 (pause) I try not to think like that but (pause) (upset here, tears)

113  
114 **I'm sorry Jane**

115  
116 One of my appointments with Dr XX emmm, it was just one of the recent  
117 appointments (pause) emm Dr XX knows that I'm a real worrier anyway,  
118 emmm and emm I've got the bipolar and emm, I do really worry sometimes I  
119 do really worry but eh I was (pause) speaking to him and he did put my  
120 mind at rest, emm (pause) he says, he also worries he says I worry too

Difficult emotions  
Feeling down/worried

Change - Life  
restricting

Uncertainty

Emotional impact -  
fear/worry

repeat word 'down' + pauses  
when explaining feelings

- Impact of this on her  
thoughts/feelings/behaviour  
Life restricting

repeat 'scared'

fear - impact of HF  
worry about the future 'in case  
I die young'

Describes herself as a  
worrier

repeat word 'worry'

Participant 1 Jane. Duration: 60.03

Living with a Severe Mental Illness and Heart Failure. Researcher: Michelle Rankin

Worry

Fear  
Uncertainty

Support from  
others

Life restricting  
Change

121 about my patients he says I go to bed at night sometimes I cant sleep coz  
122 hes worried emm and then he says, I'll go for long walks and he went, but  
123 you, I'm not worried about you, so that was good, that was good to hear coz  
124 hes a really good doctor, he knows his stuff when it comes to, heart emm so  
125 that that felt, I felt good hearing that. I still, it still does scare me sometimes  
126 that that I could die young  
127

128 **What's like having people like Dr X involved in you care, whats your**  
129 **thoughts on the support you get?**  
130

131 Dr X is a brilliant doctor, he's a brilliant doctor emm I I trust him and I take  
132 his word for it, but the other the other (pause) part of me and I don't know if  
133 that's where (pause) my own mental illness comes in I still do worry about it  
134 but I don't emm, disbelieve the doctor an that I'm more than happy with dr x  
135 and, em I've now been transferred to a heart nurse as well so I think thats  
136 because I'm getting this new drug today so they need to monitor me with  
137 this new drug and see how I go coz they're starting me off like with a small  
138 dose so I think they're looking to increase that as well (ok) but eh the care I  
139 get is good, I'm I'm happy with the care, sometimes I feel as if I could be  
140 doing more to help myself like emm cardiac rehab rehabilitation and  
141 exercise and things (pause) coz Im (pause) as I says its life restricting,  
142 emm, I could feel energetic for eh an hour or so and I'll do some house  
143 work eh I'll try and do a food shop and after that I'm absolutely exhausted,  
144 it's just absolutely exhausting and then again there's other days where I'm  
145 not doing anything and I'll feel totally drained and exhausted, emm, its just  
146 horrible  
147

148 **I was going to ask what that was like**  
149

repeat "worry"

thinking about future, what  
might happen

Trust in doctor

limited resilience

still worries

Could do more to help  
herself

Challenges that she faces  
on a daily basis.

"It's just terrible"



## Appendix 14: Case Study (Jack)

Jack is a 48-year-old man who lives with heart failure and body dysmorphic disorder. He started having mental health difficulties when he was in his early 20's but he doesn't like talking about what was going on for him at the time so he didn't do into detail about this. He feels there is a lot of "stigma" around going to see psychiatrists and psychologists, which he doesn't like.

A few months before Jack got diagnosed with Heart Failure (HF) his mother died. She had suffered for four weeks before she died and for Jack it had a "horrible impact sitting back watching somebody die in front of you ". He said that when his mother died it "took all the fun out of everything" and that "nothing is the same anymore". He "took it quite bad" and he went into a depression and locked himself in his room following her death. He "attributed" a lot of the stress of his mother's death to him developing HF a few months later.

Leading up his diagnosis of HF, Jack had been told that he had a bad flu, and had been given antibiotics. However, he woke up one morning and his body was all swollen and he could barely breath. He tried to make an appointment with his GP, but couldn't get one, and by that point he felt he was getting more ill so he took himself to A&E, where he then ended up staying in hospital for a week. They "did various tests and things" and they told him that his "heart wasn't pumping properly" and they put him on "a lot of beta blockers and water pills". He said that finding out he had HF was a "bit of a shock" and the experience of being told he had HF was "frightening". One of the things he was shocked by was that he didn't think he had "anything that should cause HF", and he found it hard to see why he "had to come down with it". He even laughed when he said this. He did say that it runs in the family, and as mentioned, he worries that the stress of coping with his mother's death may have brought it on. Jack also seems to worry a lot that he may have caused his heart failure and that maybe it could have been prevented. He said that he thinks that he "just worried too much and brought it on", that he worries about "everything and anything" and that this "maybe takes its toll on the heart after a while". When describing what he is like as a person he said that he is all "doom and gloom".

When Jack got discharged from hospital following his diagnosis, he said that he got "quite a lot of medication to take home" and he found this "scary". He said that he



wasn't told about what he should or shouldn't do, they just monitored his medication. He feels that now he doesn't find his treatment plan difficult. He did say that initially he found going to appointments "daunting" and that he gets "awful nervous" going to appointments as he's "not a big fan of hospitals" and that after diagnosis he had "never been to hospital so much" in his life. Now he feels it's "not as bad" as what he'd thought. But he does feel that managing his medication can be a bit of a "nuisance" as he says he keeps forgetting to take them. However, he has implemented a strategy to help him remember which is, before bed, he will take the medication "out of their packets and leave them out on the table just to remind me to take them" in the morning.

Jack described what may be considered to be conflict in relation to his feelings about medication, and what he gets told in relation to side effects of medication. For example, in relation to medication for his heart, he said that he "doesn't like medication that mucks around with the heart" but that he would rather just take the medication and not know what it does to the heart as it "really freaks you out". He said that he feels his nurse explained his heart medication well and gave him a leaflet that listed all different kinds of medications. He told me not all the medications applied to him but that he did read the leaflet and that he found this to be useful.

When he was talking about medication for mental illness, such as anti-psychotics, he explained that some of the noted side effects on the leaflets was a "hell of a thing" and would put the "fear of death in you" and that he felt it was "irresponsible". Jack said that he felt that more could be done to make people aware of side effects. He feels that there is a lot of "controversy" and that he had been watching documentaries such as panorama that "scared the wits" out of him. He feels "they could better explain that type of medication". He said that he had "to look a lot of that stuff up" himself, and he feels that a booklet or leaflet should be provided so that people could take it home to read up on it.

It is possible that Jack may be annoyed/upset that he hadn't been clearly informed about the potential side effects of the anti-psychotic medication he had been taking. He said that he had been taking it for years and that one "avenue" that doctors were looking at was the possibility that the anti-psychotic medication may have caused his

HF, and that that's why they have decided to take him off it. This may be why he feels that that more information should be provided before prescribing this kind of medication.

Jack seems to have spent a lot of time trying to make sense of why he got HF. It feels that there are a few things he has considered, the anti-psychotic medication, which is possibly why he feels so strongly that more information should be provided to him. The second thing he has considered is the amount that he worries.

It feels like Jack has tried to seek an answer (such as reading up on side effects of anti-psychotic meds etc) but hasn't been able to get a definite answer and so as a result, he has made changes to his lifestyle and he avoids things for fear of what might happen. For example, he doesn't go out much because he worries that he'll go outside and fall and "might bring on a heart attack". He also feels that only he can help himself, he doesn't see what anyone else can do and doesn't feel anyone can help him with the worry he feels about his actions bringing on a heart attack.

He talked about some of the changes he has had to make since being diagnosed with HF. Even though he said he wasn't told to do so by anyone, he has changed what he eats, he eats a lot more fruit and has cut out "junk food such as "fry ups" and doesn't drink alcohol anymore. He used to go jogging, play football, rugby, socialise a lot and go on the bus a lot but doesn't do any of that now as he "worries in case something will happen". He said that he will "stay in quite a lot now and that he doesn't "really venture out too much outside". He said that it's "just a fear that something's going to happen, that he might take a heart attack" or that he might "walk down the road and suddenly collapse". He used the word "worry" a lot when discussing this.



## Appendix 15: Emerging Themes from Interviews

Mary	Jane	Jack
<p><b>Experience of being ill</b></p> <p>"I was terrified, it was terrifying" (23) (16-24, 42-51, 67-68, 72-78, 90-94, 185-203, 220-227, 477-481)</p> <p>"I just couldn't cope" (being so ill) (11-12, 42-45, 99-102, 107-112, 127-129, 133-134, 145-146, 166-169, 179, 188-195, 224-227, 240-244, 272-279, 292-297, 312-314, 463-469, 549-554)</p> <p>"I brought it all on myself" (Cause) (16-19, 42-51, 95-102, 143-146, 435-441)</p> <p>"The voices were so real to me" (43-46, 56-58, 76-78, 82-86, 90-96, 185-188, 193-197, 201, 203, 213-227, 258-268, 451-457, 473-482)</p> <p>"I was just glad I was alive" (Relief) (242-274, 353-357, 430-436, 533-535)</p>	<p><b>Experience of illnesses</b></p> <p>"I was in a bad way" (being so ill) (7-8, 15-22, 26-41, 45-69, 144-146, 150-159, 163-172, 196-197, 203-211, 215-230, 238-242, 259-268, 345-350, 378-379, 453-487, 506-508)</p> <p>"I just took on too much" (Cause) (196-197, 201-205, 394-396)</p> <p>"I've got a heart that's impaired" (diagnosis) (68-77, 89-96, 320-324)</p> <p>"I could die young" (47-48, 88-89, 109-112, 116-126, 125-126, 131-133, 335-341, 346-350)</p> <p>"I just couldn't breath" (45-46, 65-72, 171-172)</p>	<p><b>"It's frightening"</b></p> <p>"it was a bit of a fright, yeah" (Diagnosis) (26-27, 50-54)</p> <p>"it puts the fear of death in you" (Taking medication) (86-88, 214-215, 218-226, 536-537)</p> <p>"Might bring on a Heart Attack" (uncertainty/fear of something happening) (100-113, 481-496, 679-684)</p>
<p><b>"I'm not the same person" (Change)</b></p> <p>Loss of job "when it stopped, it stopped dead" (116-128, 544-554)</p> <p>You're not the same person that you were" - Change of who I was, and what I could do (166-174, 369-370, 374-383, 387-400, 415-419, 430-435, 544-554)</p>	<p><b>"It's life restricting" (Change)</b></p> <p>"I couldn't do what I used to be able to do" (95-96, 100-101, 141-159, 163-172, 183-184, 371-374, 478-479)</p> <p>"I spend more time in the house" (Going out) (183-184, 371-374)</p> <p>"I used to love walking" (100-101,</p>	<p><b>"I don't do things I used to" or "I just don't want to set my heart off" (change)</b></p> <p>"A fear that something's going to happen" (avoid going out) (100-103, 454-464, 492-496, 691-694)</p> <p>"I'm eating a lot healthier food" (Diet) (261-263, 325-334, 657-659, 667-672)</p> <p>"I cut out all the running and stuff" (Exercise and hobbies) (445-456, 467-476)</p>

<p>"it's a pest, sometimes it's just not worthwhile going out" (278-279, 583-586)</p> <p>"I just seem to eat all the time" (Diet/weight) (415-419, 577-586)</p>	<p>441-447)</p> <p>"I didn't touch another cigarette again" (163-167)</p> <p>"I've never been a chunky person" (Diet/Weight) (415-425, 440-447, 458-459)</p> <p>"I would like a lifestyle change" (414-428, 442-447)</p> <p>"I'll miss a dose but I think that's quite normal" (Medication) (71-73, 101-104, 135-138, 334-350, 385-392, 452-453)</p>	<p>"I've lost a bit of weight" (275-276, 282-285, 348, 667-668)</p> <p>"a wake up call to start slowing myself down" (748-764)</p> <p>It's a bit of a nuisance actually" (Medication) (93-94, 100-103, 109-113, 186-226, 253-285, 293-296, 382-386, 393-403, 511-532, 542-583, 798-800, 848-849)</p> <p>"I don't like going to doctors at the best of times" (Going to appointments) (238-241, 317-318, 353-356, 362-363, 609-610, 640-645, 812-813)</p>
<p><b>Role of others</b></p> <p>"At first I was getting it all mixed up, then they organised me a blister pack" (practical help) (143-146, 232-236, 256-257, 329-333, 342-357, 366-370, 482-487, 498-501)</p> <p>"I mighta been sitting in all day, feeling low, and he's cheered me up" (Emotional support) (23-24, 72-78, 133-146, 190-194, 250-252, 565-573)</p> <p>"The doctor was saying one thing and I knew it was another" (82-91, 220-221, 256-258, 319, 453-456, 474-482)</p>	<p><b>Role of others</b></p> <p>"it just tore the heart out of every one of us" (grief) (192-211)</p> <p>Emotional support "I'll always be indebted to my mum" (230) (stop worry, reassurance) (116-126, 131-140, 182-185, 246-259, 274-280, 320-324, 328-329, 333-338, 463-473, 480-483)</p> <p>"She says to try slimming world" (Practical support) (e.g. with medication, lifestyle advice) (229-232, 335-341, 390-393, 433-447)</p> <p>"They decide she's fine" (236-242)</p>	<p><b>Role of others</b></p> <p>"when my mother died I took it quite bad" (123-124, 713-722, 734-737)</p> <p>"Never mentioned what it's supposed to do" (10-11, 260-263, 302-303, 338, 368, 858, 883, 889-892, 958-960)</p> <p>"Try to manage it myself" (independence/embarrassment/stigma) (232-233, 238-241, 246-247, 313-315, 325-328, 333-334, 353-356, 368, 376-377, 437-438, 510, 812-813, 830-831, 889-892)</p>
	<p><b>Emotions associated with illness</b></p>	<p>"I worry about this and I worry about that" (158)</p>

	<p><b>"It was very, very scary" (Fear) 31-32, 46-48, 57-60, 66-70, 86-90, 109-112, 124-126, 320-324, 400-402)</b></p> <p><b>"Just an instant relief" (69-70, 72-77, 83-85, 124-126)</b></p> <p><b>"I do really worry sometimes" (94-96, 117-120, 131-133, 321-324, 336-341, 394-402, 443-446, 468-473)</b></p> <p><b>"It's horrible" (45-46, 60-61, 150-151, 201-205, 232-235, 293-296, 484-487, 494-496, 507-508)</b></p> <p><b>"it just tore the heart out of every one of us" (loss) (192-211)</b></p>	<p><b>"Maybe I just worried too much and brought it on" (cause) (42, 123-124, 129-130, 136-144, 150-159, 183-192, 714-718, 734-737, 727-728)</b></p> <p><b>"I still feel a bit dizzy now and again" (Side effects of medications) (196-209, 203-209, 218-226, 512-514, 548-553, 571-578, 848-849, 934-942)</b></p> <p><b>"I'm worried in case something happens to me" (100-113, 454-456, 460-464, 481-482, 501-507, 691-694)</b></p>



## **Appendix 16: Major Research Project Proposal**

### **DOCTORATE IN CLINICAL PSYCHOLOGY**

**Name of Assessment:** Major Research Proposal

**Title:** Living with a severe mental illness and heart failure

**Matriculation Number:** 2141042R

**Date of submission:** 13.12.2017

**Version number:** 9

**Word count:** 3589 (excluding appendices)

## **Background**

People living with a severe and enduring mental illness are at greater risk of developing heart failure (HF) than the general population (Blom, Cohen, Seldenrijk et al., 2014). This is due to the risks associated with antipsychotic medication and health behaviour risks, such as poor diet, lack of exercise, smoking, use of alcohol etc. Nonadherence to treatment regimens is common for people who have a severe mental illness, and also people with HF. Thus, nonadherence is likely to be an issue for people with comorbid mental illness and HF. At present little is known about the experience of people with both of these illnesses, and the factors which influence adherence to their treatment regimen.

## **Aims**

The aim of the current study is to describe the experience of people with severe mental illness and HF. Specifically, to determine patients' understanding of their condition and the factors influencing treatment adherence.

## **Methods**

This qualitative study will recruit between 5-10 participants. Their interviews will be analysed using Interpretative Phenomenological Analysis.

## **Applications**

It is hoped that this study will help provide a dialogue to aid our understanding of patients' experience of their comorbid illness, and the factors associated with adherence to treatment regimens.

## **Introduction**

Heart failure occurs when the heart fails to pump blood around the body as effectively as it used to (The British Heart Foundation (BHF)). There are over half a million people in the UK living with heart failure (HF). The most common causes of HF are a heart attack, high blood pressure and diseases of the heart muscle, known as cardiomyopathy. People who experience severe and enduring mental health problems such as, psychosis, schizophrenia and bipolar disorder, are at greater risk of developing serious heart problems like HF, compared to the general population (Blom, Cohen, Seldenrijk et al., 2014; Correll & Nielson, 2010; Laursen, Munk-Olsen & Vestergaard, 2012; Nielson, 2011; Ifteni, Correll, Burtea et al., 2014). This is in part due to the risks associated with prescribed antipsychotic medication and also behavioural health risks such as poor dietary habits, smoking, use of alcohol, obesity, living a sedentary lifestyle etc. (Shulman, Miller, Misher & Tentler, 2014).

### *Adherence to a treatment regimen*

Adherence has been defined as the “active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a therapeutic result” (Ho, Bryson & Rumsfeld, 2009). Virtually all health treatments require some degree of behaviour change on the part of the patient (Levensky & O’Donohue, 2006). This may involve behaviours such as, engaging in regular exercise, following a diet, smoking cessation, attending clinic appointments, adhering to medication etc. Making these changes may be inconvenient, require a lot of effort and cost, and cause adverse effects. These issues may lead to low adherence or nonadherence. Low or nonadherence to treatment plans can take many forms: attending appointments late or not attending appointments at all, not taking medication or taking medication incorrectly (too few, or too many pills), not initiating the treatment regimen or ending the treatment regimen prematurely.

Nonadherence to treatment plans is a growing concern for clinicians and health care providers (Ho et al., 2009). There are substantial health, social and financial costs associated with nonadherence (Levensky & O’Donohue, 2006). For example, for the patient, nonadherence compromises the effectiveness of the available treatment, it increases the risk of relapse, it interferes with recovery, it can lead to hospitalisation and in many cases, it can lead to death (De las Cuevas, Penate & Cabrera, 2016; Owen-Smith, Stewart, Green, Ahmedani et al., 2016). For the physician and healthcare system, nonadherence questions the effectiveness of the treatment recommendations, and it increases costs, such as costs associated with patient relapse and hospitalisation etc.

Even in ordinary circumstances, adherence can be difficult to maintain (Prochaska, DiClemente & Norcross, 1992). It is not surprising then that for people with chronic and multifaceted illnesses, adherence may be somewhat complex. People with a severe psychiatric disorder (psychosis, schizophrenia, bipolar disorder) and HF are prescribed medications for their illness (an antipsychotic such as clozapine), and they are likely to have been prescribed a range of medications for their heart, in many cases two to three different types. In addition to this, it is most likely that they will be advised to make some lifestyle changes such as engaging in some form of exercise, stopping smoking and changing their dietary habits (BHF). The extent to which these patients adhere to their medication regimen and follow the advice provided is currently unknown. However, research has shown that medication nonadherence is common in patients with schizophrenia (Gilmer, Dolder, Lacro, Folsom et al., 2004; Haddad, Brain & Scott, 2014; Nelson, Graham, Lindsey & Rasu, 2011; Owen-Smith et al., 2016) as well as in patients with HF (Chin & Goldman, 1997; Cole, Norman, Weatherby et al., 2006). Factors such as: illness severity, treatment complexity, cost, lack of illness awareness, social isolation, comorbid substance misuse, stigma and poor access to appropriate medical care (Haddad, Brain & Scott, 2014; McDonald, Garg & Haynes, 2002; Santiago, 2016) all impact a patient’s ability to comply with their treatment plan.

### *Determinants of adherence*

Understanding and addressing adherence difficulties is crucial for improving patient care, improving outcomes and lowering treatment costs (Haynes, McDonald, Gang & Montague, 2002). Research into adherence has identified common factors/themes that may predict whether a person will adhere to their treatment regimen. For example, one factor identified is in relation to the treatment itself: the complexity of the treatment regimen to be followed, the cost required to adhere to the treatment. If the treatment is complex and costly, patients are less likely to adhere. Sociodemographic factors have also been found to negatively impact patient adherence, for example, lack of a good support system, high level of social deprivation.

Perhaps the most extensively researched factors are patient-related factors, such as, a patient's personality, their beliefs, motivation, self-efficacy, or whether they are depressed. These are all factors that have been shown to impact a patient's level of adherence (Christensen, 2004). These different characteristics and health beliefs have been integrated into structured models, which attempt to predict health beliefs and health behaviours. The Health Belief Model (Becker & Rosenstock, 1987), Self Determination Theory (Deci & Ryan, 2000) and Stages of Change Model (Prochaska & DiClemente, 1986) are examples of models that have been developed to understand and predict health beliefs and health behaviours. However, reviews of the literature have generally concluded that there is little or no association between patients' beliefs identified in the above models, and adherence to treatment (Christensen & Johnson, 2002; Dunbar-Jacob & Schlenk, 2001). Furthermore, there is little evidence to suggest that other factors, such as personality traits and sociodemographic factors are also related to adherence (Christensen & Johnson, 2002; Dunbar-Jacob & Schlenk, 2001).

Christensen and colleagues (2002; 2004), (based on research by Higgins, 1990), suggest that attempts to identify traits or dispositions that predict behaviour are of limited usefulness without also considering the context, or situation, that an individual is facing. Instead, they consider the joint or interactive effects of patient/characteristic factors along with the context of the treatment regimen (severity of the illness, type of treatment) (Christensen, 2004). From this perspective, it is the interactive effect of patient factors and contextual factors that most strongly influences behaviour (Christen & Johnson, 2002). For example, research has shown that individuals who have more active coping styles show a better response to treatment that is under their control (doing exercise, taking medication at home) rather than under the control of the therapist (e.g. treatment administered in hospital). In contrast, patients who tend to show a less active coping style, or who disengage from stressful situations tend to show better adherence when the treatment is therapist led (Dance & Neufeld, 1988; Christensen, Smith, Turner & Cundick, 1994). By gaining an understanding of the interaction between a patient's traits, beliefs, coping styles and the type of treatment they are undergoing, interventions can be tailored appropriately, increasing the likelihood of good adherence to the treatment plan.

### *Managing severe mental illness and heart failure*

Factors found to negatively impact adherence for someone with a severe and enduring mental illness are: patient-related factors such as attitudes and past behaviours, comorbid conditions, symptom severity, medication-related factors, and environmental factors (Velligan, Weiden, Sajatovic, Scott et al., 2009). Similarly, factors found to negatively impact adherence for someone with HF are: patient-related factors such as depression and anxiety, comorbid conditions, and problems with the health-care system (Riegel et al., 2009). Patients facing at least one of these illnesses have been found to struggle to adhere to their treatment plans, and effort has been made to understand and address this (Loffler, Kilian, Toumi & Angermeyer, 2003; Marder, Essock & Miller et al., 2004; Nielson, 2011; Riegel & Carlson, 2002; Riegel, Moser, Anker et al., 2009; Saha, Chant & McGrath, 2007). Many of the factors found to impact adherence in one of these serious illnesses is likely to affect someone who experiences both serious illnesses. However, at present, the extent of this is unknown. As the risks are even greater for these patients, it is essential that research is conducted to determine their experience of their illness, to understand the factors influencing nonadherence which in turn should help guide the best treatment regimen.

### *Positioning the study*

Interpretative Phenomenological Analysis (IPA) is a qualitative research method, which explores the idiographic subjective experiences of individuals, how they ascribe meaning to their experiences and how they make sense of their world (Biggerstaff & Thompson, 2008). Through reflective interpretation, the researcher becomes an active agent in the lived experiences of the participants (Braun & Clark, 2013; Smith & Osborn, 2008).

This seminal study will be the first to explore the experiences for people with both severe mental illness and HF, and hopes to inform the literature base about this otherwise previously unknown topic.

### *Aim*

The aim of the current study is to describe the experience of people with severe mental illness and HF. Specifically, to determine patients' understanding of their condition and the factors influencing treatment adherence.

## **Method**

### *Design*

This study utilised Interpretative Phenomenological Analysis (IPA). IPA explores how individuals make sense of their social world, with a focus on finding the meanings that are attached to specific experiences (Smith & Osborn, 2008). IPA has roots in epistemology while also focussing upon 1) phenomenology, a philosophical approach concerned with lived experience 2) double hermeneutics, whereby the researcher attempts to make sense of the individual who is making sense of their own

experiences 3) idiographic in-depth exploration of individual cases (Smith, Flowers & Larkin, 2009). In accordance with IPA methodology, purposive homogeneous sampling was utilised such that participants were selected due to their experiences of living with both a diagnosis of a severe mental health difficulty and a diagnosis of HF, and the in depth insight they can provide in to these experiences.

### *Participants*

Participants were English speaking patients, over the age of 18, who were diagnosed and receiving treatment for HF and had a recorded and/or patient reported diagnosis of schizophrenia, psychosis or bipolar disorder. They were prescribed either a mood stabiliser (lithium) or an anti-psychotic (e.g. clozapine, olanzapine, risperidone, quetiapine) to treat their mental illness. They were judged to be in a stable condition (based on clinical judgement of the clinical team in the first instance, and then by researcher's clinical judgement at initial telephone contact, and on day of interview) with no coexisting medical comorbidity. Potential participants were excluded if they had a diagnosed learning disability, cognitive impairment, or were currently unstable (e.g. psychiatric hospitalisation within the last 6 months). Those who were not competent in understanding questions in English were also excluded. A total of six potential participants were identified but excluded. One person was receiving palliative care, one had recently been admitted to hospital, two were cognitively impaired and two were judged by the clinical team to be too unwell to participate. Five potential participants who met inclusion criteria were identified. One potential participant DNA'd his appointment and, as a result, could not be recruited within the study timeframe. The second potential participant decided he did not wish to participate in the study.

### *Procedure*

Prior to commencing recruitment, ethical approval was obtained from the East of Scotland Research Ethics Committee (Appendix...) Research and Development Management Approval was obtained for NHS GGC (Appendix...), and Caldicott guardian approval from NHS GGC was obtained (Appendix...). Recruitment took place between October and March 2018. There were two methods of recruitment. The first method was via consultation with staff from the cardiology teams throughout NHS GGC. HF nurses, pharmacists and cardiologists were provided with standard information leaflets and were asked to consider, in collaboration with researcher, patients on their caseload who may be eligible for inclusion in the study. The second method involved obtaining patient CHI numbers from databases to match up patients who have HF and who are taking anti-psychotic medication. A list of HF patient CHI numbers will be obtained from each HF team. A list of patients who are on antipsychotic medication will be obtained from the Psychological Clinical Information System (PysCIS database, NHS GGC). The CHI numbers will be transferred onto one database and matching CHI numbers will be identified.

Researcher will then contact the HF team, highlighting the CHI number (at this stage no other identifying information will be given to researcher). Researcher and HF nurse/cardiologist will discuss eligibility for the study. Approval from NHS GGC Caldicott Guardian will be sought and all data collected will be stored on a NHS computer and password protected, only accessible to the principle researcher.

Participants were informed about the study via carer groups and staff of NHS Lanarkshire's Forensic Mental Health Service, as well as Support in Mind Scotland. Staff were given information about the study (Appendix 7) and recruitment posters were placed in forensic mental health service venues (Appendix 8). Staff were encouraged to identify suitable participants and provide them with the Participant Information Sheet (PIS) (Appendix 6). In addition, with permission the researcher visited the NHS Lanarkshire forensic carers group and delivered a short presentation about the study. The PIS containing the contact details of the researcher was left for those interested in finding out more about the study. Those interested were asked to provide contact details to a staff member which were then returned to the researcher. The researcher then contacted the person to answer any questions and establish if they wished

to participate. Following this, an interview was arranged for those who agreed to participate. Written informed consent was obtained prior to commencing the interviews (Appendix 9). Interviews were held in clinic rooms of local NHS venues.

### *Methods*

A semi-structured interview guide was developed to address the main research aim and according to IPA guidelines (Smith, Flowers & Larkin, 2009). The suitability of this guide was discussed and developed with the research and field supervisor. Expert clinicians working with patients with HF were also consulted for guidance. A pilot interview was conducted in order to ensure the interview is feasible, and to determine any risk factors. Interviews were approximately one hour in duration.

### *Participants*

Three participants were recruited for the study. These patients were receiving treatment for HF and on antipsychotic medication to treat their mental illness. The study included both males and females, over the age of 18. Socio-demographic information such as age of participant, diagnosis, occupation and postcode was also gathered.

### *Inclusion and Exclusion criteria*

People will be eligible to participate if they are aged 18 years and over, have had a diagnosis of HF for at least one year, and have a recorded and/or patient reported diagnosis of schizophrenia, psychosis or bipolar disorder. Participants will have been prescribed a mood stabiliser (lithium) or an anti-psychotic (e.g. clozapine, olanzapine,

risperidone, quetiapine) as well as medication related to HF. They must be in a stable condition (based on clinical judgement of the clinical team in the first instance, and then by researcher's clinical judgement at initial telephone contact, and on day of interview) with no coexisting medical comorbidity.

To safeguard against risk, participants will be excluded if they have a diagnosed learning disability, cognitive impairment, or are currently unstable (e.g. psychiatric hospitalisation within the last 6 months). Those who are not competent in understanding questions in English will also be excluded.

### *Recruitment Procedures*

It is proposed that there may be two methods of recruitment for the study. The first method will occur through consultation with HF nursing staff and cardiologists throughout NHS GGC. Researcher will liaise with HF nursing staff and cardiologists to explain the nature of the project, the eligibility criteria and also to get a sense of potential recruitment numbers. HF nurses and cardiologists will be provided with standard information leaflets. HF nurses and cardiologists will be asked to consider patients on their caseload who may be eligible for inclusion in the study. Researcher will collaborate with nurses and cardiologists to identify patients who meet the criteria for the study. (i.e. over 18, prescribed anti-psychotic medication, clinical judgement from clinical team that patient is physically and mentally stable). At this stage, no patient identifiable information will be available to researcher.

The second method involves obtaining patient CHI numbers from databases to match up patients who have HF and who are taking anti-psychotic medication. A list of HF patient CHI numbers will be obtained from each HF team. A list of patients who are on antipsychotic medication will be obtained from the Psychological Clinical Information System (PysCIS database, NHS GGC). The CHI numbers will be transferred onto one database and matching CHI numbers will be identified. Researcher will then contact the HF team, highlighting the CHI number (at this stage no other identifying information will be given to researcher). Researcher and HF nurse/cardiologist will discuss eligibility for the study. Approval from NHS GGC Caldicott Guardian will be sought and all data collected will be stored on a NHS computer and password protected, only accessible to the principle researcher.

Once identified, and agreed upon via consultation with the nurse, researcher and supervisors, the researcher will take note of next clinic appointment, and will remind nurse leading up to the appointment date, so that nurse remembers to pass on study details to their patient. During the clinic appointment, nurse/cardiologist will outline details of the study, and information sheets will be provided, to be given to potential participants. Nurse/cardiologist will let their patients know that they can contact the researcher to discuss the study (contact details provided on information sheet). Also, researcher will be available during clinic time (in another clinic room) so that if patient does want to discuss study, or has any questions, then researcher can be made



available for this. At this stage, there will be no attempt to obtain consent for the study.

At this clinic appointment: if the person decides they wish to participate, they let their nurse/cardiologist know who will then inform the researcher, passing on contact details. The researcher will contact potential participant via telephone. During this initial telephone call the researcher will remind potential participant about the details of the study and the fact that participation is voluntary. A pre-screen will be conducted to determine current mental state and overall wellbeing, to determine if person is still eligible to go ahead with the study. They will also be asked to report on their mental health diagnosis (as it may not be clear in medical notes). They will be informed that a letter will be sent to their GP and nurse/cardiologist to make them aware that their patient is participating in the study. Following this, and if clinically judged by researcher to be stable, an interview will be arranged.

At the interview, if potential participants are still keen to participate, written consent will be obtained. It will be explained that all details from the interview, and responses of the participant will be anonymised. At this stage, interview will only be conducted if participant is clinically judged by researcher to be currently mentally stable to do the interview.

Timeline of recruitment pathway:

1. Researcher liaises with clinical team to identify potential eligible participants. Also, a search of HF CHI numbers and PsyCIS database CHI numbers will be completed to identify any matches. If patient/s identified from the database, researcher will then contact HF nurse to discuss eligibility. At this stage, researcher will only have access to CHI numbers, no other patient identifiable information will be given).
2. Researcher takes note of next clinic appointment with patient (again researcher only has access to patient's CHI number at this stage).
3. At next clinic appointment, nurse/cardiologist provides details of study, gives information sheet etc. Researcher will be available in another room if patient has any questions they would like answered.
4. If verbal consent is given at this appointment, researcher will then contact patient via telephone (at least 24 hours later), remind of study, do pre-screen to assess stability, and arrange interview time, if eligible.
5. Interview to be conducted if participant is judged by researcher to be in a stable condition.

### *Data Analysis*

The data will be transcribed verbatim by the researcher. Data will be analysed using IPA. Guidelines for analysis as described by Smith, Flowers and Larkin (pp. 79- 108, 2009) will be adhered to. The stages of analysis are as follows:

1. Initial transcription. Close reading and re-reading of the text, noting thoughts, reflections and observations that occur.
2. Interview themes are identified, capturing the essential qualities of the interview. Psychological terms and concepts may be used at this stage (Willig, 2008).
3. Related themes are developed into clusters or concepts and subordinate categories are identified.
4. The process is repeated for all transcripts, maintaining a willingness to engage with new themes that may emerge.
5. A 'master' list, or summary table of themes is compiled.

### *Justification of sample size*

A sample size between five and 10 will be sought. It has been suggested that fewer participants examined at a greater depth is preferable (Hefferon & Gil-Rodriguez, 2011).

### *Settings and equipment*

Interviews will be conducted in a hospital clinic or, if possible, a GP surgery that is convenient for the participant. Each interview will be conducted in a quiet room with the researcher and participant. All interviews will be audio recorded.

The recordings will be transferred onto an encrypted laptop and transcribed by the researcher. The encrypted laptop will be held in a locked cabinet, at the University of Glasgow. The recordings will be backed-up and saved on a password protected part of the University of Glasgow network, only accessible to the principle researcher. All potential identifiers of persons or places will be anonymised. Data will be stored in accordance with University and NHS guidelines.

## **Health and Safety issues**

### *Researcher safety issues*

All interviews will be conducted within the working hours of each service/clinic. The interviews will only be conducted while other staff members are on site. Regular supervision meetings will be arranged with the research supervisors to coincide with interviews.

### *Participant safety issues*

Consultation with potential participants' referrer (e.g. HF nurse) will allow for discussion regarding risk and safety issues. Potential participants will be given an information sheet prior to opting in to the study. Written consent will be obtained before the interviews and participants will be made aware (documented in information sheet, written consent form and explained verbally before the interview begins) that

they can opt out at any time. They will be made aware that they have the option to bring someone they know along to the interview.

It may be difficult for participants to discuss their illness and difficulties associated with managing their illness. There may also be comorbid mood issues as research has shown that approximately 48% of patients with HF experience clinically significant levels of depressive symptoms (Dekker et al, 2009). Therefore, participants will be made aware of the focus of the interview and explained to them that some of the questions may be difficult for them. They will be made aware that they can stop at any time if they feel they do not want to continue with the interview and the researcher will regularly check-in with the participants to ensure that they are happy to continue with the interview. If a participant does become upset, the interviewer will stop, apologise for causing distress and allow participant to decide what they would like to do, i.e. continue, take a break or end the interview.

### **Ethical issues**

Ethical issues to be considered are in relation to the potential distress associated with taking part in the study. This will be considered by the research team and in consultation with the referrer (e.g. HF nurse who knows the person). Every effort will be made to ensure that participants are aware of what is expected of them and what is involved in taking part. They will be reminded that they can opt out of the interview at any point with no consequence for themselves.

The project will be submitted to NHS R&D management for approval.

Ethical approval will be obtained from the East of Scotland Research Ethics Service.

### **Financial issues**

Equipment costs will amount to one digital voice recorder (to be borrowed from the University of Glasgow), travel costs for participants to attend a clinic that is most convenient to them, and photocopying costs.

### **Timetable**

Timetable agreed by the University of Glasgow:

5<sup>th</sup> December 2016: Draft of the proposal to be submitted to academic supervisors.

30<sup>th</sup> January 2017: Proposal submission to the university.

28<sup>th</sup> February 2017: Final approval of MRP proposal and associated paperwork.

31<sup>st</sup> March 2017: Ethical applications to be made.

23<sup>rd</sup> October 2017: Interviews to commence.

24<sup>th</sup> February 2018: Interviews to be concluded.

The research will be written up into a thesis in the University of Glasgow and published into Clinical Psychology Journals. All publications will be anonymous, and no participant will be identifiable from their stories. Each participant will receive a

copy of the findings. It is hoped that the findings will be presented at conferences also.

## **Practical Applications**

Understanding the experiences, difficulties and barriers to adherence by patients with a severe and enduring mental health problem and heart failure will help guide health care staff to develop appropriate interventions/treatment plans to best support patients.

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